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Supreme Court of the United States

FALKO-GUNTER FALKNER, GEORG HOLZER, and FRIEDRICH DORNER,

Petitioners,

v.

STEPHEN C. INGLIS, MICHAEL E.G. BOURSNELL, and ANTHONY C. MINSON,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Federal Circuit interpreted and applied the disclosure requirements of 35 U.S.C. § 112 in a manner that is contrary to the U.S. Constitution and the patent laws by awarding a patent for an invention to those who do not disclose that invention nor how to make and use it in the requisite full, clear, concise and exact terms.

LIST OF PARTIES AND RULE 29.6 STATEMENT

The names of some of the parties appearing before the U.S. Court of Appeals for the Federal Circuit appear in the caption of the Petition for Writ of Certiorari. The real party in interest for Petitioner is Baxter AG of Vienna, Austria, 10% or more of which is owned by Baxter Healthcare Corporation of Deerfield, Illinois.

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OPINIONS BELOW

The opinion of the U. S. Court of Appeals for the Federal Circuit is reported at 448 F.3d 1357 (2006), which affirmed the judgment of the Board of Patent Appeals and Interferences of the U.S. Patent and Trademark Office ("the Board"). The opinion of the Federal Circuit was authored by Circuit Judge Gajarsa. The opinion and judgment of the Board is not reported.

JURISDICTION

The judgment of the Federal Circuit was entered on May 26, 2006, and a petition for a rehearing and rehearing *en banc* was filed by Petitioner, and denied without comment by the Federal Circuit on August 24, 2006. The jurisdiction of the Federal Circuit was based upon 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. §§ 141, 142. This Court's jurisdiction is based upon 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISION

U.S. Const. art. I, § 8, cl. 8:

> The Congress shall have Power . . .
>
> > To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

STATUTORY PROVISION

35 U.S.C. § 112, paragraph 1:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

INTRODUCTION

One of the stated goals of this Court is to resolve conflicts in the circuit courts of appeals. Where as here a conflict openly exists among the judges of the U.S. Court of Appeals for the Federal Circuit over interpretation of the disclosure requirements (written description and enablement) of the patent laws, resolution of that conflict by this Court is proper. Where as here the conflict among Federal Circuit judges concerns the Constitutional underpinnings of our patent laws, namely the disclosure requirements for a patent, action by this Court is even more fitting. Where as here those judges who have competing ideological differences are repeatedly unable to convene *en banc* proceedings to resolve their differences and speak with one voice, action by this Court becomes imperative. And where as here, judges of that court charge that their colleagues created an "opaque"[1] and "ill-defined general disclosure doctrine [that] imperils the integrity of the patent system"[2] to the point where applicants are told in essence "'[b]ring your specifications to the Federal Circuit and we will tell you if they contain sufficient descriptions,'"[3] immediate resolution by this Court becomes vital to an American public that is increasingly impacted by the legal and financial power of granted patents.

The decision below by a panel of the Federal Circuit reflects one of the court's two competing ideologies. In this case, the prevailing ideology was that which believes that only the thinnest of disclosures is necessary, which disclosures may be supplemented, often years later, by experts and inventors who cite the earlier disclosures of others to prove *nunc pro tunc* entitlement to a patent. On the merits alone, the panel's approach was so clearly at odds with this Court's jurisprudence as to

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1. *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 433 F.3d 1373, 1376 (Fed. Cir. 2006) (Rader, J., dissenting).

2. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 982 (Fed Cir. 2002) (Rader, J., dissenting).

3. *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 433 F.3d 1373, 1379 (Fed. Cir. 2006) (Rader, J., dissenting).

warrant review and repair by this Court. Just as compelling, however, the increasing conflict in the Federal Circuit jurisprudence on this issue means that such panel-dependent results will continue indefinitely until such time as this Court intervenes to instruct the Federal Circuit on the requirements imposed on the patent system by the United States Constitution and the patent laws.

The Constitution granted Congress the express power to establish a patent system to promote the progress of science by rewarding inventors with a limited period of exclusivity for their inventions. Article I, § 8, cl. 8 of the Constitution provides two requirements. First, there must be a promotion of the progress of science; and second, the award must be granted to an "inventor" who has made a discovery. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). In return for disclosure, the inventor receives an "exclusive Right to their . . . Discover[y]." U.S. Const. art. I, § 8, cl. 8.

The section of the patent laws of primary importance here is the first paragraph of 35 U.S.C. § 112, which requires inventors to provide a

> written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

Indeed, as explained by this Court:

> [T]he patent laws require[] that the patent application shall include a full and clear description of the invention and "of the manner and process of making an using it" so that any person skilled in the art may make and use the invention. . . . When a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the

> public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure, which disclosure it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.

Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (footnote omitted).

The patent laws provide incentives to inventors to undertake the risks involved in technological development, but in exchange require disclosure of those technological developments by the inventor to the general public through the patent specification, which when disseminated to the public by the issued patent will stimulate further technological development. *Id.* at 480-81. In other words, the patent system "embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989). The patent system provides two means for promoting technological development, namely (1) it rewards inventors as encouragement for advancing technological development, and (2) it requires, in exchange, a "full, clear, concise, and exact" disclosure of the invention to the public such that the public can freely practice the invention upon expiration of the patent term, and then make further advances in science. The keys are thus *creation* and *disclosure* of a new, useful and nonobvious advance in technology. *Id.*

STATEMENT OF THE CASE

Summary

The present case involves a patent interference[4] between party Falkner (Petitioner) and party Inglis to determine which

4. A patent interference is a procedure in the Patent Office to determine which inventor among competing putative inventors was the first to invent and describe an invention, and thereby merit a patent. 35 U.S.C. § 135. Patent interferences have led to important developments

(Cont'd)

party first invented a vaccine based upon genetically engineered poxviruses ("modified poxvirus vaccine"). The decision involves the written description and enablement requirements of the first paragraph of 35 U.S.C. § 112, and this petition concerns the errors committed by both the Board and the Federal Circuit panel on review.

Unfortunately for patentees and the public alike, the errors committed by the Board and Federal Circuit panel here are unsurprising given the ongoing, tumultuous conflict in the Federal Circuit over the disclosure requirements of Section 112. The conflict concerns whether there exists a separate written description requirement in the patent laws, and if so, whether it requires disclosure in the specification beyond enabling an invention and how should such a requirement be applied. This conflict has repeatedly bubbled to the surface through conflicting panel decisions, with eruptions occurring most notably in three reported decisions denying *en banc* rehearings to clarify the dispute as to the disclosure requirements of Section 112. The strongly worded dissents from these three decisions to deny *en banc* reconsideration demonstrate the breadth of the chasm between the judge's conflicting views of the statutory disclosure requirements of Section 112. As Judge Newman candidly observed in her dissent from one of the court's denials of *en banc* reconsideration, the Federal Circuit written description controversies have "percolated enough." *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1305 (Fed. Cir. 2004). Indeed, the conflict among the Federal Circuit judges, which also is predictably reflected in ongoing scholarly disputes in the field, has percolated enough. This issue is ripe for resolution by this

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(Cont'd)

in the patent laws. For example, *Brenner v. Manson*, 383 U.S. 519 (1966) involved a patent interference to claims for certain steroids. In *Brenner*, this Court determined the fundamental question of what is considered a useful invention. In this case, this Court can determine an equally fundamental question, namely what constitutes an adequate disclosure of a useful invention.

Court, and for reasons discussed below, this case squarely presents the issue that must be resolved.

The applications of Inglis are primarily directed to different vaccines made from herpesviruses, and the entirety of Inglis' disclosure relating to the modified poxvirus vaccine comprised only two sentences. The first merely referenced a type of poxvirus (*i.e.*, vaccinia) as a possible virus for making vaccines in the future, and the second expressly acknowledging that such a vaccine had not been made:

> As another example the virus may be derived from an orthopox virus [types of poxviruses], for example, vaccinia virus, which again may comprise a heterologous sequence encoding an immunogen derived from a pathogen.

Inglis PCT application at page 6, line 26 to page 7, line 4. A420-21.

> No vaccinia virus [a type of poxvirus] with a deletion in an essential gene has yet been produced, but such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine vector.

Inglis PCT application at page 15, lines 1-5. A429.

In the initial Patent Office proceeding, the Board awarded the right to a patent for the modified poxvirus vaccine to Inglis, but at the same time also made a diametrically contradictory ruling. That ruling – unappealed by Inglis and therefore law of the case – plainly held that Inglis' Patent Cooperation Treaty (PCT)[5] application did not disclose the modified poxvirus vaccine:

> Inglis has failed to explain why we should construe the referenced disclosure as being directed to a

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5. The Inglis PCT application, *inter alia*, was relied upon by Inglis to support an early priority date. App. 6a n.3. The Inglis PCT was assigned serial no. PCT/GB91/01632, and was published as WO 92/05263. A413.

> defective poxvirus lacking a function imparted by an essential region of the parental poxvirus. Moreover, the remainder of the context from the cited portion of the reference discusses the "reluctance to use unmodified vaccinia on a large scale in humans." We do not understand that an "unmodified vaccinia virus" would be understood to mean a "defective poxvirus that lacks a function imparted by an essential region of its parental poxvirus." App. 63a; A49.[6]

In affirming the judgment of the Board, the Federal Circuit panel simply lost sight of the constitutional and statutory goals of the patent system, as well as this Court's precedent, and awarded a right to a patent to party Inglis, whom the Board held did not disclose the modified poxvirus vaccine.

Under even a most permissive reading, Inglis' two sentence disclosure cannot constitute "a full and clear description of the invention and 'of the manner and process of making an using it' so that any person skilled in the art may make and use the invention. . . ." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974). Moreover, although Petitioner pointed out the inconsistency in the Board's judgment, the panel did not address how the Inglis applications could simultaneously disclose and not disclose the same modified poxvirus vaccine.

The panel also did not reconcile Inglis' earlier, contradictory statement to the Patent Office that, in comparison to herpesvirus, a poxvirus was a "different virus family with a grossly different intracellular cycle." A733. As support for the affirmance, the Federal Circuit panel believed that Inglis' disclosed herpesvirus example served a surrogate teaching for the missing poxvirus teachings, and thus based a poxvirus patent award on herpesvirus subject matter that, as admitted by Inglis, is entirely distinct from poxvirus. App. 14a.

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6. Citations to "App. ___a" are references to the appendix for this petition. Citations to "A___" are references to the Joint Appendix filed with the Federal Circuit.

Technology and the Proceedings Below

There exist of myriad of different viruses in the world, the effects of which range from benign to deadly. For example, rhinoviruses are responsible for the common cold and rarely causes serious illness. Herpesviruses cause cold sores, genital infections, shingles and chickenpox (old terminology for the childhood illness that bears no relation to the poxviruses). Hepatitis viruses are implicated in liver disease, including liver cancer. One of the world's most dangerous viruses is the smallpox virus (a poxvirus), which is highly contagious, has about a 30% mortality rate, and has reemerged as a national security concern in our post-9/11 world. Because the structures, characteristics and effects among viral families are so different, there is no virus family that serves as an archetype for all other virus families. A245-343.

The interference in this case related to modified poxvirus vaccines containing poxviruses[7] that are genetically engineered to lack a function of an essential poxvirus gene, thereby rendering such poxviruses incapable of propagating under normal circumstances and thus safer to work with.[8] The

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7. The patent interference was limited to poxviruses. Poxviruses include the virus known as variola, which causes smallpox. A 'cousin' of variola is vaccinia, which is used as the smallpox vaccine. Vaccinia possesses antigens (*i.e.*, characteristic proteins) that are sufficiently similar to those of variola that vaccinia can stimulate an immune response in vaccinated recipients that will prevent an infection by variola. Vaccinia is an infectious poxvirus, although it is relatively benign in healthy recipients. However, vaccinia can cause severe illness in the very young, the elderly and immuno-compromised patients, such as patients undergoing chemotherapy or suffering from AIDS. Despite the limitation to poxviruses, the Federal Circuit mentioned that the Inglis applications also contain generalizing text that is allegedly applicable to "*any virus*. . . ." App. 13a (emphasis in original). Such text is attained merely by deleting "herpes" from the word "herpesvirus" by common word processing techniques, and therefore does not provide a universal teaching that applies to all viruses.

8. In order to propagate the mutant poxviruses of the interference, they must be grown in genetically engineered cells that contain the (Cont'd)

interference was declared because Petitioner's U.S. Patent No. 5,770,212 ("the '212 patent") and Inglis' application serial no. 08/459,040 ("the '040 application") claimed the same vaccine containing these poxviruses. The interference "count," which defines the contested-invention, consisted of Petitioner's patent claim 1 and Inglis application claim 29. In summary, the count was directed to vaccines composed of (1) defective poxviruses that lack a function imparted by an essential region of the parental poxvirus, wherein that function could be complemented or (2) mutant poxviruses that have an inactivating mutation in a viral gene that is essential for production of new virus particles, wherein the mutant poxvirus can be produced in a complementing host cell. App. 4a-5a. The two clauses of the count are deemed synonymous.

Petitioner's first patent application disclosing the modified poxvirus vaccine was filed on April 29, 1994. This application was followed by a "continuation-in-part application" filed on March 14, 1996.[9] A further "divisional" application was filed

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(Cont'd)

essential gene that the mutant poxvirus has been engineered to lack. Because these mutant poxviruses cannot complete a lifecycle in normal cells, they are not infectious in normal cells and cannot cause disease in humans. This development makes these poxviruses safer and easier to handle. A112. These poxviruses optionally can be further genetically engineered to express the antigens of other pathogens as well, such as the AIDS virus (HIV). A219-21. Falkner's U.S. Patent No. 5,770,212 ("the '212 patent") discloses mutant poxviruses (*e.g.*, vaccinia) that encode an HIV gene and lack an essential poxvirus region, and are capable of expressing HIV proteins as well as poxvirus proteins during growth, but only when grown with complementation, such as in a complementing cell. A117-19. Such a poxvirus can be used as a vaccine because it can stimulate the production of anti-poxvirus antibodies and anti-HIV antibodies in an vaccinated recipient by virtue of the engineered poxvirus having both poxvirus antigens and HIV antigens.

9. A "continuation-in-part" application repeats disclosure from a parent application and provides additional disclosure to the application.

on February 21, 1997.[10] The '212 patent involved in the interference issued on June 23, 1998. App. 6a; A102. During the interference, the Board accorded Petitioner the benefit of priority of each of these applications, determining that Petitioner had disclosed the modified poxvirus vaccine invention in the 1994 application and subsequent applications. App. 6a. Inglis did not contest the benefit of priority awarded to Petitioner. The '212 patent is due to expire on April 29, 2014, which is twenty years after the earliest filing date.[11]

Inglis first filed British applications in 1990 and 1991, which were followed by the filing of an international application known as a "PCT application" in 1991 and thereafter a chain of U.S. applications filed from 1992 to 1995 (Inglis' applications from 1990-95 are collectively referred to as "the Inglis priority applications"). App. 6a. Petitioner contested by motion the according of benefit to Inglis priority applications on the ground that they lacked a sufficient disclosure of a modified poxvirus vaccine under Section 112, *i.e.*, they lacked both written description and enablement of the modified poxvirus vaccine.[12] App. 27a, 56a. The Inglis '040 application, by virtue of its pre-GATT filing date, is eligible for a seventeen year term from its issue date. The Inglis application would likely issue in 2007 or later, and thus would have a term that expires no later than 2024.

10. A "divisional" application repeats disclosure of the parent application but has different types of claims.

11. The '212 patent has a filing date (February 21, 1997) that was after the implementation of the General Agreements on Tariffs and Trade (GATT) on June 8, 1995, and thus is entitled only to a twenty year term from the earliest claimed filing date. Patent applications filed before the GATT implementation receive the longer of a seventeen year term from the issue date or twenty years from the earliest filing date.

12. To obtain the benefit of priority under 35 U.S.C. §§ 119, 120, 365, *i.e.*, credit for the filing date, of an earlier application, that application must support the claims in a manner that satisfies 35 U.S.C. § 112. To obtain a patent, the application in question must also satisfy 35 U.S.C. § 112. Because the pertinent text of Inglis priority applications and '040 application are essentially the same, the analyses of each is the same.

The Federal Circuit decision thus delays the public's freedom to practice the modified poxvirus vaccine invention by 10 years or more.

At the same time that Petitioner moved to deny Inglis the benefit of its priority applications, Inglis cross-moved to invalidate Petitioner's patent claims on the ground that one of the Inglis priority applications, the Inglis PCT application (WO 92/05263, published in 1992) disclosed the same modified poxvirus vaccine. Hence, Inglis argued that the Inglis PCT application published in 1992 "anticipated" Petitioner's patent claims that have a first filing date of 1994. App. 59a-64a.

The Board rendered diametrically inconsistent decisions on these motions. It denied Petitioner's motion to deny Inglis the benefit of the Inglis priority applications, determining that there was a sufficient disclosure of the modified poxvirus vaccine in the Inglis priority applications, including the Inglis PCT application.[13] App. 27a-56a. But at the same time, the Board also denied Inglis' motion, determining that the Inglis PCT application did not anticipate nor render obvious the modified poxvirus vaccine because it did not sufficiently disclose the modified poxvirus vaccine. App. 59a-64a. Citing to page 14 of the Inglis PCT application (A428), a page relied upon by Inglis as disclosing the modified poxvirus vaccine,[14] the Board stated:

> Nevertheless, the disclosure at page 14 is directed to the ability of vaccinia virus, a particular, well-known virus, to "carry and express genes from

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13. Accordingly, Inglis was awarded all priority dates back to 1990, and thereby was considered the first 'inventor' and entitled to the patent. Petitioner's first filing date is in 1994.

14. Notably, the lengthy passage quoted by the Federal Circuit panel of its decision to support affirmance and eventual grant of the patent on modified poxvirus vaccines to Inglis (App. 13a) cites the very same Inglis application text, pages 14-15 (A428-29), that the Board found did not disclose a defective poxvirus of the interference. App. 63a; A49. Vaccinia modified in non-essential (*i.e.*, inessential) genes is 1982 prior art, and formed no part of the interference. App. 2a-3a.

> various pathogens" and the use of a vaccinia virus modified to carry and express genes from various pathogens as an effective vaccine in animals. Inglis has failed to explain why we should construe the referenced disclosure as being directed to a defective poxvirus lacking a function imparted by an essential region of the parental poxvirus. Moreover, the remainder of the context from the cited portion of the reference discusses the "reluctance to use unmodified vaccinia on a large scale in humans." We do not understand that an "unmodified vaccinia virus" would be understood to mean a "defective poxvirus that lacks a function imparted by an essential region of its parental poxvirus."
>
> Thus, Inglis has failed to provide a sufficient factual basis on which we could find Falkner's claims [including claim 1 of the count] are "anticipated by the proferred reference [the Inglis PCT application]. App. 63a; A49.

The Board judgment that the Inglis PCT application did not anticipate nor render obvious Petitioner's claims, and thus did not disclose the modified poxvirus vaccine of the interference, was not cross-appealed by Inglis. Therefore, this judgment is law of the case. Unfortunately, the Federal Circuit did not address the impact of this unappealed judgment.

Despite this conflicting Board judgment, the Federal Circuit made the following conclusions and findings:

(1) The Board erred in its articulation of the written description standard, but that error was harmless (App. 15a).

(2) The Inglis applications described virus vectors generally, could be applied to any virus, and focused on herpesvirus vectors, including the provision of a detailed example for herpesviruses (App. 12a-14a);

(3) The differences between herpesviruses and poxviruses were known, which would have allowed the skilled person

to apply the lessons of the herpesvirus example to make a poxvirus according to the count (App. 14a);

(4) The Inglis applications contained at least three passages that mentioned poxvirus, although the Inglis applications did not disclose an actual reduction to practice for the poxviruses recited in the count (App. 12a);

(5) Although poxvirus essential regions for use with the invention are not described in the Inglis applications, poxvirus essential genes were known to exist (App. 19a-20a);

The Federal Circuit's decision, however, sidestepped the flaws that were apparent in the Board's logic and raised by Petitioner on appeal. First, the panel did not address the Board's determination that the Inglis PCT application did not sufficiently disclose the modified poxvirus vaccine so as to anticipate or render obvious Petitioner's claims to that vaccine and yet contained sufficient written description to merit a patent to Inglis claiming that very same vaccine.[15] Second, the panel also declined to explain how Inglis' two-sentence muse about the future creation of vaccinia [poxvirus] vaccines, combined with Inglis' disclosure of a herpesvirus vaccine, could be considered a sufficient disclosure of a modified poxvirus vaccine given Inglis' earlier admission to the Patent Office that herpesvirus is a "different virus family with a grossly different intracellular cycle" as compared to poxvirus. A733.

To award Inglis a patent term of seventeen years for providing these two sentences is simply an affront to the "carefully crafted bargain" that the patent system represents.

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15. Before the Federal Circuit, Inglis argued in rebuttal that the cross motion was denied because they did not show disclosure of a "heterogene" in their PCT application, not because the Inglis PCT application did not disclose a modified poxvirus vaccine. See Inglis Response to Combined Petition for Rehearing and Petition for Rehearing En Banc by Appellant Falkner at page 7. Neither the count, Petitioner's claim 1 nor the Board's decision mention the term "heterogene," however, and thus this rebuttal argument is without merit.

Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-51 (1989). Inglis' two sentences are not a description that promotes the progress of modified poxvirus vaccines, and certainly do not provide "a full and clear description of the invention and 'of the manner and process of making and using it' so that any person skilled in the art may make and use the invention . . ." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974). To allow the Federal Circuit decision to stand would not provide Inglis with an award to their discovery, but rather would award Inglis with Petitioner's discovery, and thus would be contrary to Art. 1, § 8, cl. 8 of the Constitution. Unless this Court corrects the panel's decision, therefore, the Patent Office will have granted a patent and seventeen-year monopoly to Inglis for an application that the Patent Office expressly found did ***not*** disclose the modified poxvirus vaccine — a very odd bargain indeed. Indeed, absent intervention by this Court, the public's freedom to practice the modified poxvirus vaccine invention will be set back 10 years to the year 2024 — a heavy price to be paid for two sentences that do not disclose the modified poxvirus vaccine.

REASONS FOR GRANTING THE PETITION

This case deserves review on its merits because to grant Inglis a patent for a modified poxvirus vaccine based on their two-sentence afterthought does a grave disservice to the patent laws, particularly in view of the contradictory, unappealed holding of the Patent Office that the Inglis priority applications do not disclose the modified poxvirus vaccine. Just as important, this case is of profound significance to the American public because the unresolved conflict raging among the Federal Circuit judiciary means that litigants' fates will be decided not on the basis of legal principles and *stare decisis*, but on the luck of the draw and ideological leanings of their particular appellate panel. There can be no doubt that the Federal Circuit is in turmoil, albeit well-intentioned, over the disclosure requirements of the patent laws. However, in addressing these issues the Federal

Circuit has not referred back to the Constitution and this Court's long-standing case law for guidance. And because the Federal Circuit has been unable to right its ship through *en banc* review, this case also is profoundly important because otherwise the court will continue to issue conflicting opinions that mirror the widely divergent beliefs of the individual judges.

This Court's interpretation of the patent laws has been consistent and clear

A patent must contain a written description of an invention in "full, clear and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science." *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 381-82 (1822). Crude and imperfect experiments are insufficient to support a patent grant — rather an invention exists only where a party has reduced it to practice[16] in some type of physical and distinct form. *Seymore v. Osborne*, 78 U.S. (11 Wall.) 516, 552 (1870); *see also T.H. Symington Co. v. National Malleable Castings Co.*, 250 U.S. 383, 386 (1919); *Clark Thread Co. v. Willimantic Linen Co.*, 140 U.S. 481, 489 (1891). This Court's early cases have been interpreted to mean that the invention must no longer be in the experimental phase in order to be complete. *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 52, 66 n.12 (1998). The invention must be complete, not just substantially complete. *Id.* at 66. In other words, the invention must be "ready for patenting," which can be satisfied by drawings or other description of the invention that are sufficiently specific to enable a person of skill in the art. *Id.* at 67-68. As noted by this Court:

> An invention exists most importantly as a tangible structure or a series of drawings. A verbal portrayal

16. Current patent law recognizes two types of reduction to practice. When an invention is actually made and shown to function for its intended purpose, the invention is considered to have been 'actually reduced to practice.' When an invention is disclosed in a patent application that satisfies 35 U.S.C. § 112 in terms of written description and enablement, the invention is said to be 'constructively reduced to practice.'

> is usually an afterthought written to satisfy the requirements of the patent law.

Festo Corp. v. Shoketsu Kinzoku Kabushiki Co., 535 U.S. 722, 731 (2002), *quoting Autogiro Co. of America v. U.S.*, 384 F.2d 391, 397 (Ct. Cl. 1967).

Thus, an inventor obtains a right to exclude others in exchange for a "full disclosure of the invention" that "describe[s] the exact scope of the invention and its manufacture." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996). An inventor must provide a full and clear description of the invention and how to make and use it such that when a patent is granted the inventor's teachings are of such importance to deserve exclusivity, and will in turn stimulate further significant advances in the art. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974). A patent is not a "hunting license" for a search for a useful invention, but rather is a reward for a successful conclusion of the search, *i.e.* a completion of the invention. *Brenner v. Manson*, 383 U.S. 519, 536 (1966).

Federal Circuit jurisprudence on Section 112 is unsettled, contradictory and panel-dependent

The panel determined that "[a]lthough the Board "erred in its articulation of the written description standard, that error is harmless." App. 15a. The panel's decision, however, shows that it was the panel that erred by not taking this Court's holdings into account. This Court has *never* sanctioned the granting of a patent to someone merely because he or she could point, *ex post facto*, to previously unreferenced prior art teachings to prove that an earlier idea could have been made to work. Rather, this Court's decisions have uniformly required a "full disclosure of the invention" that "describes the exact scope of the invention and its manufacture." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996). A patent is not a "hunting license" for a search for a useful invention, but rather is a reward for a successful conclusion of the search, *i.e.* a completion of the invention. *Brenner v. Manson*, 383 U.S. 519, 536 (1966). The patent laws require that the patent application include a full and clear description of the

invention and the manner and process of making and using it. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974).

That this panel was confused about the written description requirements of Section 112 is unsurprising. Indeed, since 2002 the Federal Circuit has been petitioned on at least four occasions for *en banc* rehearings to clarify the disclosure requirements of Section 112. Each time, the Federal Circuit has declined to do so, with no fewer than five of the judges having voted for *en banc* reconsideration at one time or another. The increasingly strong dissents by several of the court's judges from the denials of *en banc* reconsideration reveal the conflicting ideologies in the Federal Circuit over the written description required for patent disclosures, which ultimately work to the detriment of inventors and the general public.

In *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed Cir. 2002), Judges Rader, Gajarsa and Linn strongly argued in dissent that the case should have been reheard *en banc* because, they charged, the Federal Circuit since 1997 was improperly applying the written description requirement as a means to invalidate patents, rather than just for policing priority dates. The dissenting judges believed that the written description requirement imposed by the Federal Circuit created "an ill-defined general disclosure doctrine [that] imperils the integrity of the patent system." *Id.* at 982.

In *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1307 n.1 (Fed. Cir. 2004), the judges declined *en banc* reconsideration by a 7 to 5 vote. Judge Newman dissented from the denial and wrote that "the question [of whether there is a separate written description requirement and how it is to be applied] has percolated enough; it is ripe for en banc resolution." *Id.* at 1305. Judges Rader, Gajarsa and Linn wrote in dissent that disclosure must be tied to the time of filing, *id.* at 1311, and that a separate written description requirement "creates confusion as to where the public and the courts should look to determine the patentee's right to exclude." *Id.* at 1326. The dissenting judges included a lengthy appendix of articles

concerning the split views of the academic community on the Federal Circuit's written description jurisprudence.

In *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 433 F.3d 1373 (Fed. Cir. 2006), Judges Rader and Gajarsa also dissented from the denial of a *en banc* rehearing, and commented that the Federal Circuit's "written description jurisprudence has become opaque to the point of obscuring other areas of the [Federal Circuit's] jurisprudence." *Id.* at 1376. The dissenting judges opined that the Federal Circuit has been unable to develop a technology neutral standard, and thus has told applicants in essence to "'[b]ring your specifications to the Federal Circuit and we will tell you if they contain sufficient descriptions.'" *Id.* at 1379. The dissenting judges concluded with:

> As this court's case law creation strays farther from the statute, its application only gets more strained. Meantime, district courts must attempt to reconcile the inconsistencies between *Phillips* and the progeny of *Lilly*, such as *Lizardtech*. From my perspective, this court should not postpone further *en banc* reconsideration of its evolving written description doctrine.

Lizardtech, Inc. v. Earth Resource Mapping, Inc., 433 F.3d 1373, 1381 (Fed. Cir. 2006) (Rader, J., dissenting).

In late August of 2006, the Federal Circuit again denied *en banc* reconsideration for *Falkner v. Inglis*. Although the Federal Circuit provided no opinion for its denial, nothing has occurred subsequent to *Lizardtech* that has clarified the requirements of Section 112.[17] And as the panel decision in this case shows, some of the judges have clearly lost sight of the mandate of the Constitution, the patent statute and this Court's decisions to require applicants to actually disclose in their patent applications

17. Circuit Judge Rader observed that "it is apparent that a significant number of Federal Circuit judges agree that this court's evolving written description doctrine needs clarification. *** However, it is equally apparent that the court is in no hurry to clarify the issue." *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 433 F.3d 1373, 1381 (Fed. Cir. 2006) (Rader, J., dissenting) (citations omitted).

what their invention is, how to make their invention, and how to use their invention.

The discussion within the Federal Circuit centers about whether or not there is a separate written description requirement. This conflict, however, has become a distraction that is eroding the achievements of the patent system. Whether written description is a separate requirement from enablement or part of a larger requirement combined with enablement, two sides of the same coin as it were, becomes irrelevant. Congress clearly required patent applicants to provide a written description of the invention and of how to make and use it to be set forth in the patent specification in "full, clear, concise and exact terms." The Constitution only permits a patent award to inventors who have advanced the progress of science in the technology covered by the patent. Conversely, those who rely upon the prior art to fill in all of the details of their wishful thinking have neither advanced science nor made an invention. The patent system can only award inventors with an exclusive right to their discovery, not the discovery of others. The goals of the patent system for a full, clear, concise and exact disclosure of an invention in the patent specification, as this case aptly demonstrates, have become lost in the ideological dispute at the Federal Circuit.

Without binding clarification from this Court, inventors will be subjected to panel-driven decisions by the Federal Circuit. Some Federal Circuit judges will seek extensive disclosure of an invention to support a patent, whereas other judges will accept a disclosure that is as sparse as the two sentences proffered here by Inglis. And although the Panel stated that an applicant must show possession of the invention, plainly they permitted that possession of literally every detail of the structure and method of making it could be shown, *nunc pro tunc*, by undisclosed publications in the prior art instead of by the patent specification itself.

The debate is likewise raging outside of the Federal Circuit

As can be expected, academic publications have long recognized the ideological split among the judges at the Federal Circuit, and are filled with the pros and cons of each side's dogma. As pointed out in the dissent from the denial of *en banc* reconsideration in *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303 (Fed. Cir. 2004), the dissenting judges included a lengthy appendix of articles concerning the split views of the academic community on the Federal Circuit's written description jurisprudence. A plethora of published articles could be cited to illustrate the community's awareness of the problem, but the following are exemplary:

> Patent rights provide tremendous value to their owners – the right to exclude all others from making, using, and selling what the patent claims. As the quid pro quo for such rights, the federal patent laws require the inventor to describe the invention and to teach the public how to make and use the invention. As to this requirement, a debate has been brewing in the U.S. Court of Appeals for the Federal Circuit – the appellate court responsible for appeals in all cases – over whether the patent statute contains a separate "written description" requirement, or whether the description requirement is simply part and parcel of the requirement that the patent enable those in the art how to make and use the invention. The debate has been particularly fierce in the area of patents directed to pharmaceutical and biotechnology inventions. Recently, over vigorous dissenting opinions, the court has declined to address this issue as en banc court, leaving open the question of whether the Supreme Court will weigh in.
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> * * *
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> Judge Newman nevertheless advocated en banc review to avoid "continuing debate in panel opinions applying divergent law," because the debate was "disruptive of the stability with which this court is

> charged. If precedent has become obsolete or inapplicable, we should resolve the matter as a court and again speak with one voice." Judge Newman concluded that "[t]his question has percolated enough; it is ripe for en banc resolution."
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> * * *
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> Given the discordance within the Federal Circuit and the significance of this issue to the patent bar and a myriad of business sectors and most prominently, perhaps, the biopharmaceutical sectors, the Supreme Court may decide to weigh in on the debate about the written description requirement. Indeed, in light of the lack of en banc review by the Federal Circuit – at least for the time being – Judge Linn has urged the Supreme Court to review the question.

Vernon M. Winters & Elizabeth S. Weiswasser, *The Written Description Requirement: Ripe Enough? Or Is More Percolation Required?* 51 Fed. Law. 20, 23 and 25 (2004).

> After the doctrine of equivalents, non-obviousness and utility for biotechnological inventions, it is now the written description requirement which is the next in row for further clarification and uniform interpretation. The history of case law in this connection demonstrates that courts seriously struggle in finding the exact ambit of this requirement. *** In this light, it would have been a good opportunity to hear the Enzo case en banc. However, the CAFC had decided otherwise, be it that the court is clearly heavily divided on the matter. It may be hoped that one day, the CAFC will hear a case en banc in order to clarify the written description requirement, and who knows, it might also be a case for the US Supreme Court.

Sven J.R. Bostyn, *Written Description After Enzo Biochem: Can The Real Requirement Step Forward Please?* 85 J. Pat. & Trademark Off. Soc'y 131, 152 (2003).

Indeed, the ideological conflict at the Federal Circuit has resulted in Inglis being provided a patent in exchange for a two sentence disclosure — that disclosure being supplemented by hindsight citation to the prior art and to a different invention, namely herpesvirus. As explained below, in a related judgment the Patent Office held that Inglis' priority application do not disclose the modified poxvirus vaccine of the invention. Moreover, the herpesvirus disclosure relied upon by the panel (App. 13-14a.) was, as represented by Inglis to the Patent Office, inapplicable to poxviruses.

The Board's unappealed holding that the Inglis PCT application did not disclose the modified poxvirus vaccine was not addressed by the panel

As discussed above, Inglis moved during the interference to invalidate Petitioner's claims based upon the Inglis PCT application (WO 92/05263, published in 1992). App. 59a-64a. The Board thus held that the Inglis PCT application did not disclose Petitioner's modified poxvirus vaccine and that holding was not appealed by Inglis and thus is law of the case. Nevertheless, the panel held that the very same Inglis PCT application provided sufficient written descriptive and enabling disclosure to merit a patent and seventeen-year monopoly for the very same invention. Although raised by Petitioner, the panel failed to address the impact of this Board determination. In fact, as explained above, the Federal Circuit supported its decision to affirm by quoting language from pages 14-15 of the Inglis PCT application (A428-29) that the Board specifically held only concerned the prior art, and not the invention of the interference. App. 13a, 63a.

Should the Federal Circuit decision stand, the Inglis PCT application would not anticipate Petitioner's claim 1 due to lack of description, but would provide written description and enablement of the very same claim 1 as part of the count. Such a decision simply defies logic.

The panel further erred in crediting Inglis for prior art disclosures that were neither referenced nor incorporated into Inglis' priority application, but were instead gleaned years later from the prior art (with benefit of Petitioner's detailed disclosure) to support Inglis' *nunc pro tunc* claim of invention

The Inglis PCT application is representative of all of the Inglis priority applications since the applications were deemed to be "substantially similar[]" and "essentially identical". App. 6a n.3, 12a n.9. The Inglis PCT application contains twenty one pages of detailed examples and seven figures to describe how to make mutant herpesviruses lacking essential herpesvirus genes (A431-451, 455-58) even though the Inglis applications themselves admit that such mutant herpesviruses had already been created in the prior art (A418-19). The Inglis PCT application mentions poxviruses in only three passages, which are primarily directed to the poxvirus prior art and not the invention in interference. A192-93. In fact, Inglis admitted that no mutant vaccinia virus lacking an essential gene "has yet been produced" (App. 18a n.10) and that herpesvirus is a "different virus family with a grossly different intracellular cycle" as compared to poxvirus. A733.

The contrast is startling: twenty one pages of detailed examples and seven figures for herpesviruses known in the prior art versus two sentences relating to a modified poxvirus vaccine that had never before existed. Inglis had no drawings or examples of modified poxvirus vaccines and no evidence that they ever figured out how to actually make a modified poxvirus vaccine. There was no complete invention ready for patenting or deserving of a patent. *See Festo Corp.*, 535 U.S. at 731.

That Inglis disclosed not a single detail of what a modified poxvirus vaccine would look like or how to make it, however, was of no concern to the panel. They filled in virtually every detail of the invention by reference to what "would have been" discernable from the prior art, albeit now with the benefit of

Petitioner's detailed roadmap of exactly which genes and which methods could be used to make the modified poxvirus vaccines:

> Furthermore, the testimony of Inglis' expert, Dr. Boursnell, established that the articles describing essential genes for poxvirus were well-known in the art. Dr. Boursnell testified that "the skilled person would have been readily able to choose an essential vaccinia gene" based on the references that have been publicly available since 1990. The testimony of Falkner's expert, Dr. Carroll, did not refute this claim.[18] App. 16a.
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> Accordingly we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes")[19], satisfaction of

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18. Petitioner's witness Dr. Carroll testified that if it one could so easily rely on the prior art to supplement the Inglis PCT application, Dr. Boursnell surely would have done so and disclosed the prior art in the Inglis PCT application in 1991 since he was named as an inventor on that Inglis PCT application. See second Carroll declaration at A243. Dr. Boursnell and the other Inglis *et al.* inventors provided no such disclosure. *See U.S. Industrial Chemicals v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668, 677-78 (1942) (noting that if an invention was as broad as professed in litigation, "[t]he inquiry at once arises, if this were so, why he did not say so" in the patent application.).

19. As explained in Example 5 of Petitioner's '212 patent, some essential regions will work in the context of the invention, but most will not. A119-20. Inglis, however, did not identify any regions that work, nor did Inglis teach a screening method to separate candidate regions that work from those that do not. In this vein, Inglis admitted in the interference that its own disclosure "does not describe a particular example of a complementing host cell containing a named poxvirus gene," and "does not describe a particular example of inactivating a named essential poxvirus gene to make a mutant poxvirus." A1028 at paragraphs 13 and 14; A1089 at paragraphs 14 and 15. Although raised on appeal, these admissions too were not addressed by the panel.

> the written description requirement does not require either the recitation or incorporation by reference (where permitted) of such genes and sequences. App. 21a

As a threshold matter, the panel reversibly erred by failing to require from Inglis "a full and clear description of the [modified poxvirus vaccine] and 'of the manner and process of making an using it' so that any person skilled in the art may make and use the invention. . . .". *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974). Worse, however, they implicitly articulated a test for invention that permits patentees to preempt entire fields by disclosing nothing more than ideas of what might be useful, and then leaving the "details" to others to figure out through real research and innovation.[20] All a patentee need do to preempt a field such as modified poxvirus vaccines, according to this panel, is to one day retroactively allege "enablement" of his or her idea by reconstructing the prior art through the rose-colored glasses of hindsight, when the knowledge gained from others makes everything seems easy and obvious. A patent system more chilling to innovation, more counter-productive to society and more antithetical to the intent of the Constitution, Congress and decisions of this Court can hardly be imagined.

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20. The Panel credited the testimony of Inglis expert witness Dr. Boursnell, who also is named as an inventor on the Inglis applications. Dr. Boursnell testified about what the skilled person allegedly "would have been readily able to choose" even though all such disclosure was missing from the Inglis (and his own) applications. App 16a. Here, the Federal Circuit fell into the trap of allowing an expert to enlarge the scope of a patent. *See U.S. Industrial Chemicals v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668, 677-78 (1942). Ultimately, a litigation-driven *post hoc* reliance on the prior art does not result in the progress of science, as the Constitution requires. Such *post hoc* citations do not add "to the general store of knowledge. . . ." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974).

The panel also erred by failing to consider Inglis' admissions concerning the differences between herpesvirus and poxviruses

As mentioned above, Inglis devoted twenty one pages of detailed examples and seven figures for herpesviruses known in the prior art, and yet provided only two sentences relating to a modified poxvirus vaccine to be created in the future. In addition to crediting Inglis with the undisclosed prior art in order to fill in every detail of what a modified poxvirus vaccine would look like and how one could make it, the panel also credited Inglis' disclosure of herpesvirus vaccines as an enabling teaching that could be applied to poxviruses. App. 11a-20a. Indeed, the panel stated:

> Moreover, because the differences between the herpesviruses and the poxviruses were well known, this would have aided the person of ordinary skill in the art in her application of the lessons of the herpesvirus example in the construction of poxvirus vaccines. App. 14a.

Although raised by Petitioner, the panel failed to reconcile this extrapolation of Inglis' herpesvirus work with Inglis' earlier statements to the Patent Office. More specifically, during prosecution of Inglis' '040 application the examiner rejected various Inglis virus claims as obvious over combinations of prior art references, one of which involved a combination of a prior art herpesvirus reference [Hutchison] with a prior art poxvirus reference [Paoletti]. Inglis quickly distinguished the two viruses:

> The reader of Hutchison, concerned with details of herpesvirus structure and function, would not expect that Hutchison's findings had any relation to Paoletti's mutants of poxviruses, which are a different virus family with a grossly different intracellular cycle. Such a reader would have no clear motivation to do anything related to both documents. Thus, the combination of Hutchison [herpesvirus]

> with Paoletti [poxvirus] would be improper. Furthermore, even if a proper combination, it would not render obvious the present invention. A733.

Inglis' admission that one could not apply the "details of herpesvirus structure and function" to poxvirus mutants because poxviruses are "a different virus family with a grossly different intracellular cycle" completely undermined the panel's justification for crediting Inglis' herpesvirus disclosure toward a modified poxvirus vaccine. Again, despite having been raised on appeal by Petitioner, the panel never addressed Inglis' admission.[21]

Questions the Federal Circuit should have asked

Federal Circuit jurisprudence has strayed from the requirements set forth in Art. I, § 8, cl. 8 of the Constitution and 35 U.S.C. § 112. A patent in exchange for a two sentences expressing a wish cannot be what the Framers, Congress or this Court intended – a result that would have been avoided had the panel conducted its analysis by following the decisions of this Court. To this end, the panel should have asked and answered the following questions that concern the invention in interference and the patent specifications of the parties:

(Q1) Whether Inglis' specifications provide a full and clear description of a complete invention and how to make and use it by providing detailed explanations and, as necessary, drawings.[22]

(A1) Inglis provided only two sentences mentioning a wish to create the mutant poxviruses, and all other text pertained

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21. Petitioner's expert witness Dr. Carroll also testified that herpesviruses and poxviruses are so different that one virus is not a substitute for the other. *See, e.g.*, A165-72, 238, 241.

22. *Festo Corp. v. Shoketsu Kinzoku Kabushiki Co.*, 535 U.S. 722, 731 (2002); *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989). *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974).

to different subject matter, namely herpesviruses. Inglis provided no drawings, examples or detailed explanations for poxviruses.

(Q2) Whether Inglis' specification added to the general store of knowledge and promoted the progress of the science of modified poxvirus vaccines.[23]

(A2) Inglis' disclosure, directed almost exclusively to herpesvirus, advanced nothing in the science of modified poxvirus vaccines.

(Q3) Whether Inglis completed the poxvirus-based vaccine invention of the interference such that this invention was 'ready for patenting' and no longer in an experimental phase.[24]

(A3) Inglis' specification admits that the mutant vaccinia (a poxvirus) lacking essential genes had not yet been produced, and provides no information to prove that Inglis started, much less completed, development of a poxvirus-based vaccine of the interference. As the panel's decision made clear, every detail of a modified poxvirus vaccine relied upon by the panel had to be gleaned from sources outside of Inglis' applications.

A review that focused on the content of the Inglis patent specifications in relation to the modified poxvirus vaccine invention of the interference would have resulted in an analysis that satisfies the requirements of the Constitution and the patent laws as interpreted by this Court. Such a review could only have revealed that Inglis' two-sentence disclosure provided not a single detail of what a modified poxvirus vaccine looks like,

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23. *Kewanee Oil Co.*, 416 U.S. at 481.

24. *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 52, 66-68 (1998); *Brenner v. Manson*, 383 U.S. 519, 533-36 (1966); *Seymore v. Osborne*, 78 U.S. (11 Wall.) 516, 552, 20 L.Ed. 33; *see also T.H. Symington Co. v. National Malleable Castings Co.*, 250 U.S. 383, 386 (1919); *Clark Thread Co. v. Willimantic Linen Co.*, 140 U.S. 481, 489 (1891); *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 381-82, 5 L.Ed. 472 (1822).

how it is made, nor how it is used. Manifestly, such a review did not occur here; rather, the inquiry focused exclusively on whether, undisclosed teachings from outside of the Inglis application could have been cobbled together, with the benefit of hindsight, to permit one to fill in virtually every detail of the structure of the modified poxvirus vaccines and how to make and use them.

This case presents an ideal vehicle for the Court to clarify the law

This Court has consistently intervened when fundamental tenets of patent law have become so muddled that patentees and patent practitioners have faced the likely prospect that rights will be decided not on principle and *stare decisis*, but on the ideological leanings of particular judges or panels as to which decision from a spectrum of conflicting precedent should be followed. In *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 21 (1997), this Court noted that there was disagreement in the Federal Circuit relating to the doctrine of equivalents, and that the Court would endeavor to clarify it. The same was true concerning confusion over the fundamental act of claim construction. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). Yet other important issues of patent law are currently pending before the Court. Respectfully, however, there is no issue of patent law that is more fundamental to the goals and orderly conduct of the patent system than the disclosure required to merit a patent. It is beyond question that there is tumultuous disagreement on this issue, which leads to confusion in the courts, in the patent office, in the laboratory, in academia and in the bar. And it is beyond question that this conflict will not soon be resolved by legislation or the Federal Circuit itself.

CONCLUSION

This Court has long recognized the importance of the patent disclosure and of the intent of the Constitution and Congress to promote the progress of science by requiring a full, clear, concise and exact disclosure of an invention in exchange for the property right of a patent. The Federal Circuit's decision in *Falkner v. Inglis* shows that judges of that court have lost sight of these considerations. The two sentence *desideratum* provided by Inglis — devoid of any specific structure or detail of any modified poxvirus vaccine, or of how to make and use such vaccines — simply cannot amount to a disclosure of an invention and of how to make and use it in "full, clear, concise and exact terms" in a manner that results in the advancement of the science of modified poxvirus vaccines.

Abraham Lincoln, the only U.S. president to hold a patent, declared that "the patent system added the fuel of interest to the fire of genius." A patent system that rewards applicants such as Inglis with granted patents will surely quench that fire. This Court must not allow this to continue.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DATED MAY 26, 2006

UNITED STATES COURT OF APPEALS FEDERAL CIRCUIT

No. 05-1324

FALKO-GUNTER FALKNER, Georg Holzer, and Friedrich Dorner,

Appellants,

v.

Stephen C. INGLIS, Michael E.G. Boursnell, and Anthony C. Minson,

Appellees.

Rehearing and Rehearing En Banc Denied Aug. 24, 2006.

Before GAJARSA, Circuit Judge, ARCHER, Senior Circuit Judge and DYK, Circuit Judge.

GAJARSA, Circuit Judge.

This is an appeal from a decision of the Board of Patent Appeals and Interferences ("Board") in Interference No. 105,187, declared on December 24, 2003, between Falkner *et al.*, U.S. Patent No. 5,770,212 ("the Falkner '212 patent") and Inglis *et al.*, U.S. Application Serial No. 08/459,040 ("the Inglis '040 application"). The Administrative Patent Judge

(APJ) designated Inglis as the senior party. On December 29, 2004, the Board issued a final decision, holding that Falkner could not antedate Inglis' September 25, 1990 priority date, and entered judgment against Falkner on the sole count of the interference. It ordered that Falkner was not entitled to claims 1-19 of the Falkner '212 patent. It further ordered that Inglis was entitled to claims 9, 10, 29 and 30 of the '040 application. Falkner filed a timely notice of appeal. This Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. §§ 141 and 142. For the reasons discussed below, we affirm the judgment of the Board.

I. BACKGROUND

A. The Invention

Some vaccines against a virus (the "target virus") incorporate harmless fragments of the target virus's genetic material into a second virus, called a "viral vector." When a person is vaccinated, the viral vector produces harmless fragments of the target virus, ultimately conferring immunity against it. To prevent the viral vector from itself causing a harmful infection in the inoculee, it must be attenuated. Attenuation is achieved by deleting or inactivating one or more genes responsible for the vector's growth and infectiousness. However, because the vaccine is produced by essentially "growing" the vector virus (accompanied by its inserted target virus gene), attenuation makes it difficult to manufacture the vaccine. The traditional solution to this problem has been to inactivate genes known as "inessential" genes. With inessential genes inactivated, the viral vector is

substantially less pathogenic. At the same time, because the vector virus can still fully reproduce itself, albeit more slowly, the vaccine can be produced in commercial quantities. However, the traditional approach carried a disadvantage, namely the risk that the vector virus, though attenuated, could still cause a harmful infection in the inoculee.

The inventors discovered a way of making vaccines safer by deleting or inactivating an *essential,* rather than an inessential, gene from the viral vector's genome, while at the same time solving the production problem by growing the vaccines in cells that were complementarily modified to produce the absent essential viral gene product "on behalf of" the vector virus. Thus, the modified vector virus could be readily grown in these complementarily-modified cells, but not in other cells, such as those of an inoculee.

This approach is applicable to many different kinds of vector viruses, e.g., adenoviruses, herpesviruses, poxviruses and retroviruses. The subject matter of this interference, however, is directed specifically to vaccines in which the vector virus is a *poxvirus.* For many vector viruses, there is a risk that vectors that have been attenuated in essential genes can "swap" genes with the host cell genome, thereby reacquiring their deleted genes and reverting to wild-type virus. This risk can be minimized through the use of viruses that are "cytoplasmic", meaning that they are unlikely to enter the cell nucleus. Because a cell's genes are located in the nucleus, cytoplasmic viruses such as poxvirus cannot swap genes with the cell genome and possibly revert to a virulent wild-type virus.

Appendix A

B. Defining the Count and Assigning Priority

The sole count of the interference was either "[a] vaccine according to Claim 1 of Falkner's 5,770,212 patent or a vaccine according to Claim 29 of Inglis' 08/459,040 application." Claim 29 of the Inglis '040 application reads:

> A vaccine comprising a pharmaceutically acceptable excipient and an effective immunizing amount of a mutant virus, wherein said mutant virus is a mutant *poxvirus* and has a genome which has an inactivating mutation in a viral gene, said viral gene being essential for the production of infectious new virus particles, wherein said mutant virus is able to cause production of infectious new virus particles in a complementing host cell gene expressing a gene which complements said essential viral gene, but is unable to cause production of infectious new virus particles when said mutant virus infects a host cell other than a complementing host cell; for prophylactic or therapeutic use in generating an immune response in a subject.

(emphasis added)

Claim 1 of the Falkner '212 patent reads:

> A vaccine comprising (a) a defective poxvirus that lacks a function imparted by an essential region of its parental poxvirus, wherein (i) said defective poxvirus comprises a DNA polynucleotide

encoding an antigen and said DNA polynucleotide is under transcriptional control of a promoter, and (ii) the function can be complemented by a complementing source; and (b) a pharmaceutically acceptable carrier.

The Administrative Patent Judge (APJ) designated claims 1-19 of the Falkner '212 patent and claims 9, 10, 29, and 30 of the Inglis '040 application as corresponding to the interference count.[1] Both parties sought the benefit of earlier-filed applications to establish dates of constructive reduction to practice.[2] The ALJ accorded the Inglis '040 application

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1. Inglis's claim 29 is his broadest claim, directed to poxvirus; and claim 30, which depends on claim 29, is a poxvirus vaccine for mammalian subjects. Claim 9 is directed to poxvirus but contains some additional limitations unrelated to the type of virus used; claim 10 depends on claim 9 and is directed to a single species of poxvirus, namely vaccinia virus. Falkner's claims 2-10 depend on claim 1. Falkner claim 10 is directed to a method of producing the vaccine of claim 1, and the remaining method claims depend thereon.

2. Priority in an interference goes to the first to invent, but a rebuttable presumption exists that the inventors made their inventions in the chronological order of their effective filing dates, namely that the senior party invented first, *see* 37 C.F.R. § 1.657(a) (2004), and the junior party bears the burden of proving otherwise, *see* § 1.657(b), such as by proving that she actually reduced the invention to practice before the constructive filing date (priority date) of the senior party, or that she was first to conceive and diligently reduced the invention to practice, starting from a date prior to reduction to practice by the senior party. *See* 35 U.S.C. § 112(g) (2000). Falkner sought to rely, in part, on an alleged date of conception and beginning of reasonable diligence: April 27, 1994.

(Cont'd)

(filed June 2, 1995) the benefit of several earlier-filed applications, dating back to September 25, 1990.[3] Likewise, the APJ accorded the Falkner '212 patent (issued June 23, 1998 from an application filed February 21, 1997) the benefit of earlier-filed applications, but these dated back only to April 29, 1994.[4] Consequently, the APJ designated Inglis as the senior party.

(Cont'd)

On September 13, 2004, the "600" rules expired in favor of new rules found at 37 C.F.R. § 41.100 et seq. However, the Board correctly chose to decide the matter under the old rules, given the parties' reliance on them in filing all motions, oppositions, and replies in the case, which were completed before the new rules took effect. *See Singh v. Brake*, 222 F.3d 1362, 1371 (Fed.Cir.2000) (applying a new procedural rule if and only if it did not affect the parties' reliance interests).

3. The Inglis priority applications were U.S. Application Serial No. 08/384,963 ("the Inglis '963 application"), filed February 7, 1995; U.S. Application Serial No. 08/030,073 ("the Inglis '073 application"), filed May 20, 1993; WO/92/05263, PCT/GB91/01632 ("the Inglis PCT application"), filed September 23, 1991, published in English on April 2, 1992; GB 9104903.1 ("the Inglis 1991 British application"), filed March 8, 1991; and GB 9020799.4 ("the Inglis 1990 British application"), filed September 25, 1990. The Inglis '040 application is a continuation in part of the '963 application, which was in turn a continuation of the Inglis '073 application. The '073 application corresponded to the Inglis PCT application. The Inglis PCT application claimed priority to, and was essentially identical to, the Inglis 1990 and 1991 British applications.

4. The Falkner priority applications were U.S. Application Serial No. 08/616,313 ("the Falkner '313 application") filed March 14, 1996; and U.S. application Serial No. 08/235,392 ("the Faulkner '392 application"), filed April 29, 1994.

Appendix A

C. Board Decision

The specifications of all of Inglis' earlier applications were similar. Although they focused on herpesvirus vectors, they contained several passages related to poxvirus-based vaccines. Because Falkner believed that these passages did not adequately describe and enable the poxvirus invention, he challenged both Inglis' entitlement to priority as to the count and the patentability of Inglis' corresponding claims. Falkner brought these challenges in three closely-related preliminary motions before the Board. In each, as the moving party, Falkner carried the burden of proof by a preponderance of the evidence. *See* 37 C.F.R. § 1.637(a); *see also Kubota v. Shibuya,* 999 F.2d 517, 520 n. 2 (Fed.Cir.1993) (explaining that "[t]he term 'burden of proof' . . . means the burden to establish the proposition at issue by a preponderance of the evidence").

Falkner brought his first preliminary motion pursuant to 37 C.F.R. § 1.633(a),[5] arguing that the claims in Inglis's involved ('040) application that corresponded to the count were unpatentable because they failed to meet the written

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5. On September 13, 2004, the "600" rules expired in favor of new rules found at 37 C.F.R. § 41.100 et seq. However, the Board correctly decided the matter under the old rules, given the parties' reliance on them in filing all motions, oppositions, and replies in the case, which were completed before the new rules took effect. *See Singh v. Brake,* 222 F.3d 1362, 1371 (Fed.Cir.2000) (applying a new procedural rule if and only if it did not affect the parties' reliance interests); *see also Brown v. Barbacid,* 436 F.3d 1376, 1379 n. 1 (Fed.Cir.2006) (holding that the Board did not err in applying the old rules "under which this case was decided").

description requirement of 35 U.S.C. § 112. In support of his argument, he stated, *inter alia,* that (1) the specification of Inglis's '040 application did not identify any essential genes in poxvirus or describe the inactivation of such genes, (2) vaccines based on vaccinia (a type of poxvirus) had not yet been produced, and (3) the bulk of the Inglis specification was directed not to poxviruses but to herpesviruses. The Board denied Falkner's motion, based in part on his failure to address the perceived shortcomings of the '040 claims in light of the specification.

Second, Falkner moved pursuant to 37 C.F.R. §§ 1.633(g) & 1.637(g) to deny Inglis the priority benefit of his earlier applications, arguing that they did not sufficiently describe and enable the claims in question.[6] Falkner argued that without the benefit of these applications Inglis would be unable to establish constructive reduction to practice earlier than Falkner. Falkner would win priority as to the count, and Inglis' corresponding claims would be unpatentable. In support of his motion, Falkner alleged deficiencies in Inglis' benefit specifications similar to those raised in his first motion. The Board carefully articulated the legal standard, correctly explaining that "benefit with respect to priority in an interference is granted with respect to *counts* not *claims*" and that "[a]ll that is necessary for a party to be entitled to benefit of an earlier filed application for priority purposes is compliance with 35 U.S.C. § 112 with respect to at least one embodiment within the scope of the count." *Board Op.* at 7

6. Falkner did not argue lack of enablement with respect to the Inglis '963 patent because he believed that the teachings of the Falkner '392 patent, filed in 1994, would have enabled the subsequent '963 patent.

(citing *Hunt v. Treppschuh*, 523 F.2d 1386, 1389 (CCPA 1975) (holding that where a "parent application is relied upon as a prior constructive reduction to practice[,] .... the § 112, first paragraph requirements need only be met for an embodiment within the count")). After careful review of the record, the Board held that Falkner had failed to meet his burden of proof.

Third, Falkner moved for judgment pursuant to 37 C.F.R. § 1.633(a) that the claims in Inglis' involved ('040) application that corresponded to the count were anticipated and therefore unpatentable. He argued that because Inglis' earlier applications had failed to adequately describe and enable the full scope of his current claims, the current claims could not be accorded the benefit of 35 U.S.C. § 120 for the purpose of antedating patent-defeating prior art.[7] The Board explained that 35 U.S.C. §§ 119 & 120 require benefit applications to comply with § 112, first paragraph, with respect to the *full scope* of what a party now claims, rather than with respect to merely one embodiment within the scope of the interference count. After carefully considering the written description and enablement issues, the Board denied the motion. As a result of the denial of Falkner's several motions, Inglis remained the senior party, and the Board ordered judgment as to the subject matter of the count in favor of Inglis.

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7. Here, Falkner points to his own U.S. Pat. No. 5,766,882 ("the '882 patent'"), issued in March 1995, as the patent-defeating prior art.

Appendix A

D. Issue and Standard of Review

On appeal, Falkner essentially reiterates the arguments that he made before the Board. While we recognize that each of these three arguments is distinct, they are nonetheless all related, and under the facts of this particular case, we need only to resolve the following common issue: whether the Inglis benefit applications adequately describe and enable a poxvirus-based vaccine. Falkner also argues that the Board committed other errors, such as initially designating Inglis as the senior party and failing to afford Falkner an opportunity for briefing prior to making this designation. These arguments lack merit, and we shall not further discuss them. We turn, therefore, to the central issues in this case: written description and enablement.

Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date. *See Vas-Cath, Inc. v. Mahurkar,* 935 F.2d 1555, 1563-64 (Fed.Cir.1991). Enablement is a question of law involving underlying factual inquiries. *See Genentech, Inc. v. Novo Nordisk A/S,* 108 F.3d 1361, 1365 (Fed.Cir.1997); *see also In re Wands,* 858 F.2d 731, 737 (Fed.Cir.1988) (holding that whether undue experimentation is required is a "conclusion reached by weighing many factual considerations .... includ[ing] (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.").

Appendix A

This court applies the standards of the Administrative Procedure Act ("APA") in reviewing decisions of the Board. *See Dickinson v. Zurko,* 527 U.S. 150, 152, 119 S.Ct. 1816, 144 L.Ed.2d 143 (1999) (holding that 5 U.S.C. § 706 governs our review of PTO appeals). Accordingly, we will set aside actions of the Board if they are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and we set aside factual findings that are unsupported by substantial evidence. *See In re McDaniel,* 293 F.3d 1379, 1382 (Fed.Cir.2002) (citing 5 U.S.C. § 706); *see also In re Sullivan,* 362 F.3d 1324, 1326 (Fed.Cir.2004) (substantial evidence review of factual findings). We review questions of law *de novo. See Rapoport v. Dement,* 254 F.3d 1053, 1058 (Fed.Cir.2001).

Substantial evidence is defined as that which a reasonable person might accept as adequate to support a conclusion. *See In re Zurko,* 258 F.3d 1379, 1384 (Fed.Cir.2001). It requires an examination of the record as a whole, taking into account both the evidence that justifies and detracts from an agency's opinion. *See In re Gartside,* 203 F.3d 1305, 1312 (Fed.Cir.2000). An agency decision can be supported by substantial evidence, even where the record will support several reasonable but contradictory conclusions. *See id.; see also In re Jolley,* 308 F.3d 1317, 1320 (Fed.Cir.2002).

II. DISCUSSION

A. Contents of the Inglis Priority Applications

The claims that correspond to the count of the interference are directed to a novel type of vaccine that is

comprised of a "vector virus" in the poxvirus family. Conceptually, poxviruses are a "subgenus" of viruses that includes the "species" vaccinia. All of the prior Falkner applications described poxvirus vaccine vectors in detail, and to the exclusion of other types of vaccine vectors (e.g., herpesvirus vaccine vectors). These applications provided five detailed working examples regarding the preparation and use of vaccines from defective poxviruses. They also described the use of a particular species of poxvirus vaccine vector, namely vaccinia virus.

In contrast, the Inglis applications described vaccine vectors in general, and then focused on the subgenus of herpesviruses, for which they provided a detailed example. Nevertheless, at least three passages discussed the poxvirus invention and specifically mentioned "vaccinia virus."[8] For example, after introducing the concept of vaccine vectors, the specification states that "[t]ypically members of the pox virus family, e.g. vaccinia virus, are used as vaccine vectors."[9]

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8. We recognize that the Inglis applications do not describe any actual reduction to practice of a poxvirus vaccine. *See Carroll Declaration* (stating that the '040 application did not contain any discussion of the "actual creation of the recited 'mutant poxvirus' " and that the application in fact stated "that a vaccinia virus with a deletion in an essential gene had not been produced."). As we discuss below, however, an actual reduction to practice is unnecessary to satisfy the written description requirement.

9. Because of the substantial similarity in the specifications of all of the Inglis benefit applications, we shall refer in this opinion to representative passages from the earliest of the applications, the Inglis 1990 British application.

Appendix A

The specification later discusses the deletion of essential genes from vaccine vector genomes, noting that the "invention can be applied to *any virus* where one or more essential gene(s) can be identified and deleted from or inactivated within the virus genome" (emphasis added). Moreover, it provides that "the virus may comprise an orthopox virus, for example, vaccinia virus, which may comprise a heterologous sequence encoding an immunogen derived from a pathogen." Finally, it reads:

> For example vaccinia virus, a poxvirus, can carry and express genes from various pathogens, and it has been demonstrated that these form effective vaccines when used in animal experimental systems. The potential for use in humans is vast, but because of the known side effects associated with the widespread use of vaccinia as a vaccine against smallpox, there is reluctance to use an unmodified vaccine in humans. There have been attempts to attenuate vaccinia virus by deleting non-essential genes such as the vaccinia growth factor gene . . . However, such attenuated viruses can still replicate in vivo, albeit at a reduced level. No vaccinia virus with a deletion in an essential gene has yet been produced, but such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine.

The application provides a detailed example of an embodiment that comprised not a poxvirus, but a *herpesvirus*, including the identity of the deleted essential sequences

therein. Nevertheless, for the reasons discussed below, we find no error in the Board's determinations on the adequacy of written description and enablement in the various Inglis disclosures.

B. Enablement

Because the adequacy of the disclosure is judged from the perspective of one of ordinary skill in the art, we start our review of the Board's decision by noting that the parties stipulated to a high level of skill in the art. They defined the skilled artisan as having 5-10 years experience creating recombinant poxvirus, as being familiar with the poxvirus literature, the use of poxvirus as a vector for the expression of heterologous genes, and having the "needed technical skill to practice the experimentation described in the scientific literature relating to recombinant virus, including poxvirus." The Board agreed with the parties' stipulation as to level of skill.

The Board did not err in finding Inglis' claims to be enabled as a matter of law, in light of its articulated underlying factual findings. In support of its conclusion, it noted that "there is extensive disclosure of the selection of an essential gene, its deletion or inactivation and the production of a mutated virus with said deleted or inactivated gene, albeit for herpesvirus." Moreover, because the differences between the herpesviruses and poxviruses were well known, this would have aided the person of ordinary skill in the art in her application of the lessons of the herpesvirus example in the construction of poxvirus vaccines. The Board observed that "the mere fact that the experimentation may have been

difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be 'undue' in this art. Indeed, great expenditures of time and effort were ordinary in the field of vaccine preparation." Thus, the Board found the Inglis applications to be enabling.

Reviewing the Board's legal conclusion of enablement, as based on its underlying findings of fact, we cannot say that the Board erred. With respect to a skilled artisan's ability to identify "essential" poxvirus genes, as discussed below we note that there was undisputed testimony that as of the time of filing of the earliest Inglis application publications in professional journals had disclosed the DNA sequence of the poxvirus genome along with the locations of the "essential regions." The person of ordinary skill in the art would clearly have possessed such knowledge, and given the ready accessibility of the journals, the absence of incorporation by reference is not problematic. Indeed, "[a] patent need not teach, and preferably omits, what is well known in the art." *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed.Cir.1987).

C. Written Description

On appeal to this court, Falkner essentially reargues the positions on written description that he took before the Board. Although the Board erred in its articulation of the written description standard, that error is harmless. The Board held that "an actual possession standard is *not* required." (emphasis added). But our precedent clearly establishes that "[t]he applicant must . . . convey to those skilled in the art that, as of the filing date sought, he or she was in possession

of the invention." *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d 1555, 1563-64 (Fed.Cir.1991). Nonetheless, we conclude there is no need for remand because the undisputed testimony supports the Board's ultimate conclusion.

As noted above, the Board found several passages in the Inglis '040 application (and in the benefit applications) that were directed to poxvirus. No length requirement exists for a disclosure to adequately describe an invention. *See In re Hayes Microcomputer Prods., Inc. Patent Litig.,* 982 F.2d 1527, 1534 (Fed.Cir.1992) ("[T]he adequacy of the description of an invention depends on its content in relation to the particular invention, not its length."). Furthermore, the testimony of Inglis' expert, Dr. Boursnell, established that the articles describing essential genes for poxvirus were well-known in the art. Dr. Boursnell testified that "the skilled person would have been readily able to choose an essential vaccinia gene" based on references that have been publicly available since 1990. The testimony of Falkner's expert, Dr. Carroll, did not refute this claim.

The parties also dispute several aspects of our law of written description, which we now address. We conclude that the Board applied correct law. Specifically, we hold, in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

Appendix A

1. Examples Are Not Required

First, it is clear that the absence of examples involving poxviruses in the Inglis applications does not render the written description inadequate. As we explained in *LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.*:

> A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.

424 F.3d 1336, 1345 (Fed.Cir.2005) (citing *Union Oil Co. v. Atl. Richfield Co.*, 208 F.3d 989, 997 (Fed.Cir.2000); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed.Cir.1995)).

2. Actual Reduction to Practice Is Not Required

As we explained in *Capon v. Eshhar*, "[t]he 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's

obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." 418 F.3d 1349, 1357 (Fed.Cir.2005). The Board was correct, however, not to view as dispositive that Inglis had not actually *produced* a poxvirus vaccine,[10] because an actual reduction to practice is not required for written description.[11] *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed.Cir.2004) ("We of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice. Constructive reduction to practice is an established method of disclosure . . . ."). *Rochester,* moreover, is consistent with Supreme Court precedent. In the context of interpreting 35 U.S.C. § 102(b), the Court held that "[t]he word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete.'" *Pfaff v. Wells Elecs.*, 525 U.S. 55, 66, 119 S.Ct. 304, 142 L.Ed.2d 261 (1998). It then proceeded to make clear that although "reduction to practice ordinarily provides the best evidence that an *invention* is complete . . . . it does not follow that proof of reduction to practice is necessary in every case." *Id.*

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10. The Inglis specifications stated that "[n]o vaccinia virus with a deletion in an essential gene has yet been produced, but such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine."

11. The Board believed that Falkner's expert, Dr. Carroll, had premised his opinions on the misunderstanding that actual reduction to practice was required to prove written description, and it discredited his expert opinion.

(emphasis added).[12] Thus, to the extent that written description requires a showing of "possession of the *invention*," *Capon*, 418 F.3d at 1357 (emphasis added), *Pfaff* makes clear that an invention can be "complete" even where an *actual* reduction to practice is absent.[13] The logical predicate of "possession" is, of course, "completeness."

3. Recitation of Known Structure Is Not Required

Falkner argues, *inter alia*, that the Inglis specifications do not adequately describe the poxvirus invention, in light of *Eli Lilly*, because they do not describe the "essential regions" of any poxvirus. 119 F.3d 1559. We note, in addition, that Inglis did not attempt to incorporate by reference any literature that described the DNA sequence of the poxvirus genome and the locations of the "essential regions." However, it is the binding precedent of this court that *Eli Lilly* does

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12. Similarly, this court has carefully explained the relationship between written description and possession, explaining that a showing of possession is not necessarily sufficient to demonstrate the adequacy of written description. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed.Cir.2002) ("[P]roof of a reduction to practice, absent an adequate description in the specification of what is reduced to practice, does not serve to describe or identify the invention for purposes of § 112, P 1. As with 'possession,' proof of a reduction to practice may show priority of invention or allow one to antedate a reference, but it does not by itself provide a written description in the patent specification.").

13. In contrast to reduction to practice, conception *is* a prerequisite to an adequate written description. *See Fiers v. Sugano*, 984 F.2d 1164, 1171 (Fed.Cir.1993) ("[O]ne cannot describe what one has not conceived.").

not set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art. *See Capon,* 418 F.3d at 1357 ("None of the cases to which the Board attributes the requirement of total DNA re-analysis, i.e., *Regents v. Lilly, Fiers v. Revel, Amgen,* or *Enzo Biochem*, require a re-description of what was already known."). Thus, "[w]hen the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh." *Id.* at 1358. Rather, we explained that:

> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.

Id. at 1357.

Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to

demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in *Capon*, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." *Id.* at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require either the recitation or incorporation by reference[14] (where permitted) of such genes and sequences.

In conclusion, having reviewed the decision of the Board, we can discern no error in its conclusion that the disclosures relied upon by Inglis for priority purposes adequately described and enabled the invention directed to poxvirus, there being substantial evidence to support these findings. Consequently, we hold that the Board's award of priority to Inglis was proper.

AFFIRMED

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14. Here, the patentee did not attempt incorporation by reference. Where, of course, certain material that is not present in the specification is deemed nonessential to the satisfaction of the written description requirement, the issue of proper incorporation by reference *vel non* is irrelevant.

APPENDIX B — DECISION AND ORDER OF THE UNITED STATES PATENT AND TRADEMARK OFFICE DATED DECEMBER 29, 2004

Paper No. 59

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

FALKO-GUNTER FALKNER, GEORG HOLZER AND FRIEDRICH DORNER URQHART

Junior Party[1]

v.

STEPHEN C. INGLIS, MICHAEL E.G. BOURSNELL, ANTHONY C. MINSON

Senior Party[2]

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1. Application 08/802,985, filed February 21, 1997, now U.S. Patent Number 5,770,212, issued on June 23, 1998. Said patent accorded benefit of: U.S. Application Serial Number 08/616,133, filed December 22, 1999, and now U.S. Patent Number 5,766,882, issued on June 16, 1998; U.S. Application Serial Number 08/235,392, filed on April 24, 1994, and now abandoned. Assigned to Immuno Aktiengesellschaft, Austria. Hereinafter, the junior party is referred to as "Falkner."

2. Application Serial Number 08/459,040, filed June 2, 1995. Accorded benefit of: U.S. Application Serial Number 08/384,963, filed February 7, 1995, now U.S. Patent Number 5,665,362, issued

(Cont'd)

Appendix B

Patent Interference No. 105,187

DECISION ON PRELIMINARY MOTIONS

Before Metz, Schafer and Torczon, *Administrative Patent Judges.* Metz, *Administrative Patent Judge*

Effective September 13, 2004, the so-called "600" rules for interferences expired in favor of the newly promulgated rules under 37 CFR §§ 41.100 (Contested Cases) and 41.200 (Interferences). On September 30, 2004, an order substituting a new Standing Order reflecting, *inter* alia, the newly promulgated rules was entered in this record. Nevertheless, all the preliminary motions, oppositions and replies in this proceeding were filed before September 13, 2004, the effective date for the new rules. Accordingly, in view of the parties' reliance on the previous rules, the motions will be decided based on the rules in effect when they were filed, that is, the so-called "600 rules." *See Singh v. Brake,* 222 F.3d 1362, 1371, 55 USPQ2d 1673, 1679 (Fed. Cir. 2000) (new rules apply except where there is a reliance by the parties on the previous rules.)

An oral hearing on preliminary motions was requested by Falkner in a paper filed September 8, 2004 (Paper Number

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(Cont'd)

September 9, 1997; U.S. Application Serial Number 08/030,373, filed May 20, 1993, and now abandoned; PCT/GB91/01632, filed September 23, 1991, published as WO 92/05263; GB 9104903.1, filed March 8, 1991; and GB 9020799.4, filed September 25, 1990. Assigned to Cantab Pharmaceuticals Research Limited, UK. Hereinafter the senior party is referred to as "Inglis."

49). The oral hearing was held on November 9, 2004, at 10:00 A.M. in the Madison Building East, 600 Dulaney Street, Alexandria, Virginia 22314. Both parties attended the hearing and were represented by legal counsel. The following motions have been filed by the parties:

1) - **"FALKNER PRELIMINARY MOTION 1",** filed June 14, 2004 (Paper Number 27); opposition filed by Inglis (Paper Number 38); reply to opposition filed by Falkner (Paper Number 45);

2) - **"FALKNER PRELIMINARY MOTION 2",** filed June 14, 2004 (Paper Number 28); opposition filed by Inglis (Paper Number 39); reply to opposition filed by Falkner (Paper Number 46);

3) - **"FALKNER PRELIMINARY MOTION 3",**filed June 14, 2004 (Paper Number 29); opposition filed by Inglis (Paper Number 40); reply to opposition filed by Falkner (Paper Number 47);

4) - **"FALKNER PRELIMINARY MOTION 4",** filed June 14, 2004 (Paper Number 30); opposition filed by Inglis (Paper Number 41); reply to opposition filed by Falkner (Paper Number 48);

5) - **"INGLIS PRELIMINARY MOTION 1",** filed June 17, 2004 (Paper Number 32); opposition filed by Falkner (Paper Number 36); reply to opposition filed by Inglis (Paper Number 43);

6) - **"INGLIS PRELIMINARY MOTION 2",** filed June 30, 2004 (Paper Number 35); opposition filed by Falkner (Paper Number 37); reply to opposition filed by Inglis (Paper Number 44).

Additionally, on September 8, 2004, Falkner filed a miscellaneous motion pursuant to 37 CFR § 1.635 captioned **"FALKNER MOTION TO SUPPRESS EVIDENCE AND STRIKE REPLIES UNDER 37 C.F.R. § 1.635"** (Paper Number 50). Administrative Patent Judge (APJ) Lee, in the exercise of his interlocutory duties, issued an order on September 9, 2004 (Paper Number 51), in which Falkner's miscellaneous motion was found to be unauthorized, was not accepted as a proper paper but was "kept in the official file for record purposes." Falkner was provided an opportunity to explain at the oral hearing why we should not consider certain arguments and evidence in Inglis' reply.

DECISION ON PRELIMINARY MOTIONS

We shall decide first those motions of each party which seek to obtain or deny benefit of an earlier filed application and which seek to redefine the interfering subject matter. These type of motions could have a bearing on which party bears the burden of proof and include the possibility of

changing the count, the vehicle by which priority is ultimately determined [3]. Thus, these types of motions may have a bearing on the scope of judgment entered in this proceeding. Each party to this interference had a full and ample opportunity to file any preliminary motion it desired within the framework set forth in the Standing Order, including a motion to redefine the interfering subject matter by changing the count or adding a count. Neither party chose to file a motion to change the count or add a count.

BURDEN OF PROOF

A party seeking to change the *status quo* in an interference by filing a preliminary motion has the burden of establishing entitlement to relief requested. The burden of proof for the moving party is by the preponderance of the evidence standard. *Kubota v. Shibuya*, 999 F.2d 517, 520-21, 27 USPQ2d 1418, 1422 (Fed. Cir. 1993); 37 CFR § 1.637(a), first sentence (1994). The preponderance of evidence burden applies even though a patent is involved in the interference.[4] Thus, the burden rests with the moving party

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3. *Barton v. Adang*, 162 F.2d 1140, 1145, 1146, 49 USPQ2d 1128, 1133, 1134 (Fed. Cir. 1998) citing *Case v. CPC Int'l, Inc.*, 730 F.2d 745, 749, 221 USPQ 196, 199 (Fed. Cir. 1984).

4. There is no presumption of validity under 35 U.S.C. § 282 of an issued patent involved in an interference. *See Perkins v. Kwon*, 886 F.2d 325, 12 USPQ2d 1308; *Lamont v. Berquer*, 7 USPQ2d 1580, 1582 (BPAI 1988). *Compare In re Etter*, 756 F.2d 852, 225 USPQ 1 (Fed. Cir. 1985) (no presumption of validity of an issued patent in reexamination proceeding); *In re Sneed*, 710 F.2d 1544, 218 USPQ 385 (Fed. Cir. 1983) (no presumption of validity of an issued patent in a reissue application).

in every instance to establish by a preponderance of the evidence that they are entitled to the relief requested in their motion.

A preponderance of the evidence has been defined as a standard which only requires the fact finder:

> to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence.

Boises v. Benedict, 27 F.3d 539, 541-42, 30 USPQ2d 1862, 1864 (Fed. Cir. 1994), quoting from *In re Winship,* 397 U.S. 358, 371-72 (1970).

FALKNER'S PRELIMINARY MOTIONS

FALKNER PRELIMINARY MOTION 2

Falkner has moved pursuant to 37 CFR § 1.633(g) to deny Inglis the benefit for each of the five earlier filed applications for which it was accorded benefit when this interference was declared. Specifically, Falkner has moved to deny Inglis the benefit of: U.S. patent application serial numbers 08/384,963 and 08/030,373; PCT/GB91/01632; GB 9104903.1; and, GB 9020799.4. Except for the 08/384,963 application, Falkner alleges that each of the priority applications "fail to comply with the written description and enablement requirements of 35 U.S.C. § 112, and therefore cannot be proper priority documents under 35 U.S.C. § 119, 35 U.S.C. § 120 and 35 U.S.C. § 365." Falkner alleges that

the 08/384,963 application, which was filed after Falkner's benefit application serial number 08/235,392 fails to comply only with the written description requirement of the statute. See page 5 of the motion.

At page 6 of the motion, Falkner correctly recognizes that the law for determining whether *claims* in an application for patent are entitled to the benefit of an earlier filed application under 35 U.S.C. § 120 is determined by determining whether the requirements of the first paragraph of Section 112 are satisfied for the *claimed* subject matter. Additionally, Falkner correctly observes that the test for whether an applicant for patent is entitled to the benefit of an earlier filed foreign application under 35 U.S.C. § 119 for the *claims* in a pending application for patent is determined by asking "whether the foreign priority application supports the claims in question in a manner compliant with the first paragraph of 35 U.S.C. § 112."

Benefit of earlier filed, prior applications under 35 U.S.C. § 119 and 35 U.S.C. § 120 for determining what is the effective date of an application under 35 U.S.C. § 102(e) is accorded with respect to what is *claimed* by an applicant. That is, under 35 U.S.C. §§ 119 and 120 the question to be resolved is: does an applicant's disclosure in the specification of the benefit application relied on satisfy the requirements of 35 U.S.C. § 112, first paragraph, with respect to the *full scope of the subject matter now being claimed by applicant.* With respect to 35 U.S.C. § 119, see *In re Gostelli,* 872 F.2d 1008, 1010, 1011, 10 USPQ2d 1614 (Fed. Cir. 1989): *Kawai v. Metlesics,* 480 F.2d 880, 885, 178 USPQ 158, 162 (CCPA 1973). With respect to

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35 U.S.C. § 120, see *In re Lukach,* 442 F.2d 967, 969, 970, 169 USPQ 795, 796 (CCPA 1971); *In re Scheiber,* 587 F.2d 59, 62, 199 USPQ 782, 784 (CCPA 1978).

Nevertheless, benefit with respect to priority in an interference is granted with respect to *counts* not *claims. Daniels v. Daum,* 214 USPQ 911 (Bd. Pat. Int. 1982). All that is necessary for a party to be entitled to benefit of an earlier filed application for priority purposes is compliance with 35 U.S.C. § 112 with respect to at least one embodiment within the scope of the count. *Hunt v. Treppschuh,* 523 F.2d 1386, 1389, 187 USPQ 426, 429 (CCPA 1975); *Den Beste v. Martin,* 252 F.2d 302, 116 USPQ 584 (CCPA 1958); *Mori v. Costain,* 214 USPQ 295, 297 (BPAI 1982); MPEP § 2309.02. Accordingly, to be grantable, any motion to deny benefit under 37 CFR § 1.633(g) must, necessarily, (1) include an interpretation of the count and (2) establish that *each* of the benefit applications for which denial of benefit is sought does not include at least one embodiment within the count as it has been interpreted and which embodiment satisfies the requirements of 35 U.S.C. § 112, first paragraph (written description *and* enablement).

Accordingly, Falkner's arguments concerning whether Inglis' benefit applications are entitled to benefit under §§ 119 and 120 of the statute are simply irrelevant to the subject motion. An application for patent may disclose an embodiment within a count and satisfy Section 112 of the statute for that embodiment and thus be entitled to priority benefit with respect to a count in an interference and not satisfy the statute for the full scope of what is claimed in application and, thus, not be entitled to benefit under §§ 119 and 120.

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Construction of counts is a question of law. *DeGeorge v. Bernier,* 768 F.2d 1318, 1321, 226 USPQ 758, 760 (Fed. Cir. 1985); *Credle v. Bond,* 25 F.3d 1566, 1571, 30 USPQ2d 1911, 1915 (Fed. Cir. 1994). Counts in an interference are given the broadest reasonable interpretation possible and resort to a party's specification to interpret the count may only be had where the count is ambiguous. *Genentech, Inc. v. Chiron Corp.,* 112 F.3d 1318, 1321, 42 USPQ2d 1608, 1612 (Fed. Cir. 1997); *DeGeorge* at 768 F.2d 1322, 226 USPQ 761; *Davis v. Loesch,* 998 F.2d 963, 27 USPQ2d 1440, 1444 (Fed. Cir. 1993); *In re Baxter,* 656 F.2d 679, 686, 210 USPQ 795, 802 (CCPA 1981). The language of the count is given its ordinary, accustomed meaning. *Johnson Worldwide Assocs. Inc. v. Zebco Corp.,* 175 F.3d 985, 990, 50 USPQ2d 1607, 1610 (Fed. Cir. 1999). Determination of whether an ambiguity exists requires consideration of both the language of the count and the reasonableness of the parties' arguments concerning the meaning of the count. *Kroekel v. Shah,* 558 F.2d 29, 31-32, 194 USPQ 544, 546 (CCPA 1977). The interpretation of the count urged by the parties in their arguments must be reasonable and not contradictory to ordinary meaning of the count. The mere fact that the parties disagree about the meaning of a term in the count does not, *per se,* raise an ambiguity as to the interpretation of the count. *Fontjin v. Okamoto,* 518 F.2d 610, 186 USPQ 97 (CCPA 1975).

Because the count in this proceeding utilizes the term "comprising" it does not exclude any other steps or ingredients not specifically recited in the count. Additionally, because the count in this interference is a so-called "bifurcated" count, the embodiment for which satisfaction

of the requirements of Section 112 must be determined can be found in *either* alternative of the count. Stated another way, the embodiment for which Inglis finds enabling and written descriptive support in their earlier filed applications may be within either alternative of the count.

The filing of an application for patent constitutes a constructive reduction to practice of *the subject matter described in the application for patent. Hyatt v. Boone,* 146 F.3d 1348, 1352, 47 BSPQ2d 1128, 1130 (Fed. Cir. 1998) and the cases cited therein. Thus, it is necessary to consider the disclosure of each benefit application as it would have been understood at *the time each benefit application was filed* and determine if what is described and enabled therein constitutes an embodiment within the count.

In its motion, Falkner has neither interpreted the count nor considered each application separately as it would have been understood on its respective filing date by the hypothetical person of ordinary skill in the art. See *Bilstad v. Wakalopulos,* 2005 WL 2248109 (Fed. Cir. 2004) ("the Board never truly discussed the understandings of persons skilled in the art and whether Bilstad's written description would reasonably convey to a person skilled in the art that Bilstad had possession of the claimed subject matter at the time of filing."). Rather, with respect to the level of skill, Falkner's motion only argues that the level of skill changed "after the filing of U.S. Serial No. 08/235,392." This constitutes at least at tacit recognition by Falkner that the disclosures of each application for which benefit was accorded must be construed as it would have been understood by a person of ordinary skill in the art at the time of each

application's filing. The five benefit applications were filed over a time period spanning five years and the level of skill over those five years and whether it changed over those five years should have been addressed in Falkner's motion.

THE WRITTEN DESCRIPTION REQUIREMENT

Whether an application for patent satisfies the "written description" requirement of the statute is a question of fact, decided on a case-by-case basis. *Vas Cath v. Mahurkar,* 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). Here, paraphrasing the court and applying the law to the count rather than the parties' claims designated as corresponding to the count the inquiry is, with respect to each of Inglis' earlier filed applications for which Falkner seeks to deny Inglis the benefit accorded them when this interference was declared, whether the disclosure of the earlier applications for which benefit was accorded reasonably conveys to the artisan that the inventors had possession at the time the earlier filed applications were filed of the subject matter of the count. *Id.*

Falkner argues that "the bulk of the Inglis priority applications concern mutant herpesviruses, not mutant poxviruses." See page 8 of the motion. Nonetheless, Falkner recognizes that the Inglis priority applications *do* contain at least three passages that specifically mention poxviruses or vaccinia. Falkner urges that the three passages are insufficient to support a finding that the benefit applications are entitled to benefit under 35 U.S.C. § 119 and 120. Falkner relies, in part, on EXHIBIT 2009, the declaration testimony of Dr. Carroll in support of this argument.

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In paragraph 24 of his declaration, Dr. Carroll recognizes that the involved Inglis application *does* disclose the poxvirus as a vaccine vector and that when used as a vaccine vector Inglis recognizes that it is important that the virus vector cause no pathogenic effects. Achieving no pathogenic effect is described as obtained by attenuation "in the same way that a simple virus vaccine is attenuated." Dr. Carroll specifically recognizes that Inglis' involved application describes a virus for use in a vaccine in which a gene has been inactivated or deleted or, alternatively, that the "mutant virus" may comprise "a heterologous sequence encoding an immunogen derived from a pathogen." Dr. Carroll further recognizes that the virus may be derived from an orthopox virus, such as vaccinia virus, and that said virus can "comprise a heterologous sequence encoding an immunogen derived from a pathogen." Finally, Dr. Carroll observes that Inglis recognizes that while no vaccinia virus with a deletion in an essential gene was known to them to have yet been produced Inglis does recognize that "such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine vector."

This disclosure from Inglis' involved application referred to by Dr. Carroll may be found almost *verbatim* in each of Inglis' priority applications for which Inglis was accorded benefit as Dr. Carroll has so-testified. See EXHIBIT 2009, paragraphs 38 and 39; 44 and 45; and 50 and 51. According to Falkner, Dr. Carroll's testimony that the above-referenced disclosures would not have shown that "Inglis et al. possessed a vaccine comprising a mutant poxvirus" mandates a finding that none of Inglis' benefit applications describe, in the sense

of 35 U.S.C. § 112, first paragraph, an embodiment within the count. See page 8 of the motion and Faikner EXHIBIT 2009, paragraph 59.

In paragraphs 36 through 50, Dr. Carroll addresses the disclosures of the various Inglis benefit applications which are, for all intents and purposes, virtually the same as the disclosure referred to above in the involved Inglis application. We also find the following additional passages from the earliest benefit application to be relevant to the issue before us. In GB 9020799.2, EXHIBIT 2016, Inglis' benefit application with the earliest filing date, beginning at page 4, line 26 and ending on page 5, line 7 it is disclosed that:

> The present invention provides an attenuated virus for use in a vaccine, in which a viral gene encoding a protein which is essential for the replication of said virus has been deleted or inactivated; and wherein said virus can be grown in a cell line which has a heterologous nucleotide sequence which allows said cell line to express the essential protein encoded by said deleted or inactivated viral gene.

On page 6, lines 13 through 16 of said benefit application, in a discussion of useful viruses from which the vaccine may be prepared, after discussing the usefulness of herpes viruses Inglis discloses that:

> Alternatively, the virus may comprise an orthopox virus, for example, vaccinia virus, which may

> comprise a heterologous sequence encoding an immunogen derived from a pathogen.

Continuing at page 6, Inglis describes the mechanism by which their vaccine is prepared, specifically that:

> a selected gene is inactivated within the virus genome, usually by creating a specific deletion. This gene will be involved in replication of the virus (but not necessarily preventing replication of the viral genome), and will thus render the virus unable to multiply in the host and produce further infective copies of the virus. This means that a viral infection cannot spread from the site of inoculation. A second feature of the invention is a cell line which provides the virus with the product of the deleted gene, thus making it possible to grow the virus in tissue culture.

See page 6, line 22 through page 7, line 6. On page 9 of the specification, Inglis outlines criteria for selecting useful "essential" genes. Specifically, Inglis discloses that the gene should be one expressed later in the infection process and the gene should be one which can be expressed at a compatible level in the complementing cell line. Ideally, the product of the gene (the protein) should itself not be toxic to the eukaryotic cell. See page 9, line 5 through page 10, line 8. At page 11, line 25 through page 12, line 3, Inglis specifically recognizes that vaccinia virus with a deletion in an essential gene in the method as described above "would provide a safer version of this vaccine vector" although Inglis recognizes that prior to the filing of its application no vaccinia

virus with a deletion in an essential gene had yet been produced.

Thereafter, the remainder of the specification is devoted to the exemplification of an embodiment within Inglis' broad disclosure. That embodiment is directed to the use of herpes simplex virus to prepare a vaccine from virus inactivated by deletion of an essential gene. The essential gene targeted for inactivation is the glycoprotein **H** gene (**gH**). Using the previously discussed criteria for selection, **gH** was selected because the protein expressed by the gene was believed to be expressed late in the infection cycle. According to Inglis, "[a]ll genetic manipulation procedures are carried out according to standard methods described in "Molecular Cloning", A Laboratory Manual, eds. Sambrook, Fritsch and Maniatas, Cold Spring Harbor Laboratory Press, 1989."

According to Falkner's arguments and Dr. Carroll's declaration testimony, the hypothetical person of ordinary skill in the art would not recognize from all the above that "Inglis et al. possessed a vaccine comprising mutant poxvirus." We disagree and we also find that in its motion Falkner has improperly focused exclusively on an actual possession standard of proof.

We find that Inglis' benefit applications reasonably convey to a person of ordinary skill in the art at the time the applications were filed a description of a vaccine prepared from a poxvirus in which an essential gene has been deleted or inactivated. Specifically, the applications include a broad statement that each is directed to "an attenuated virus for use in a vaccine" and that the attenuation is obtained by

deleting from the virus a gene encoding a protein essential for viral replication. The applications also describe a separate cell for use in combination with the attenuated virus which expresses the protein of the gene deleted from the virus and which enables the virus to grow in culture. The applications include criteria for selecting "essential" genes for deletion and specifically disclose that vaccinia virus with a deletion in an essential gene would provide a safer version of vaccinia for use as a vaccine vector. The applications disclose specific preparation of essential gene deletion variants, albeit for herpesviruses not poxviruses. Nevertheless, the applications observe that preparation of vaccines as described in the applications may be accomplished through the application of the well-known, standard techniques described in the seminal work "Molecular Cloning."

Moreover, Falkner's focus in its motion on an actual possession standard for purposes of proving description evidences a misunderstanding of the law. Indeed, it is apparent from Dr. Carroll's testimony that he focused entirely on an actual possession standard for satisfaction of the written description requirement of the statute. See, for example, paragraph 27 of EXHIBIT 2009 ("I am informed that the written description requirement means that a specification must contain sufficient disclosure to show that the inventors possessed the claimed invention.")

While it is the description found in the various benefit applications which must demonstrate "possession" of the subject matter of the count, an actual possession standard is not required. Rather, the entirety of the application's disclosure must reasonably convey to a person ordinarily

skilled in the art that the invention claimed in that application *is* the invention described in that application. In *Enzo Biochem v. Gen-Probe Inc.*, 296 F.3d 1316, 1330, 63 USPQ2d 1609, 1616, 1617 (Fed. Cir. 2002), the court observed that:

> It is true that in *Vas-Cath* we stated: "The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath,* 935 F.2d at 1563-64, 19 USPQ2d at 1117. That portion of the opinion in *Vas-Cath,* however, merely states a *purpose* of the written description requirement, *viz.*, to ensure that the applicant had possession of the invention as of the desired filing date. It does not state that possession alone is always sufficient to meet that requirement. Further, in *Lockwood v. American Airlines, Inc.*, we rejected Lockwood's argument that "all that is necessary to satisfy the description requirement is to show that one is in 'possession' of the invention." 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Rather, we clarified that the written description requirement is satisfied by the patentee's disclosure of "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Id.*

The court further explained that:

> A showing of "possession" is ancillary to the *statutory* mandate that "[t]he specification shall contain a written description of the invention" and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. After all, as indicated above, one can show possession of an invention by means of an affidavit or declaration during prosecution, as one does in an interference or when one files an affidavit under 37 CFR § 1.131 to antedate a reference. However, such a showing of possession alone does not cure the lack of written description in the specification, as required by statute.

Recently, the court has reaffirmed its holding in *Enzo* by holding that the written description requirement is "not subsumed by the 'possession' inquiry." *New Railhead Manufacturing LLC v. Vermeer Manufacturing, Co.*, 298 F.3d 1290, 1296, 63 USPQ2d 1843, 1847 (Fed. Cir. 2002).

Additionally, Dr. Carroll's testimony that the skilled routineer would have been unable to "make and use" the invention described in the benefit application without resort to additional information not found in the benefit applications is directed to the enablement requirement of the statute not the written description requirement. Therefore, Dr. Carroll's testimony on this matter is simply irrelevant to the written description issue. As the court has repeatedly recognized, the written description requirement and the enablement

requirement of 35 U.S.C. § 112, first paragraph, are separate requirements serving separate and distinct functions.

For all the above-noted reasons, we find that Falkner has failed to meet its burden of persuasion and prove by a preponderance of the evidence that the Inglis benefit applications fail to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

ENABLEMENT

The law with respect to this issue as applied to applications for a patent is clear. Whether an application for patent's disclosure is "enabling" in the sense of the statute is determined by asking whether the hypothetical person of ordinary skill in the art could "make and use" the claimed invention from the disclosure in the specification, coupled with information known in the art *at the time the application was filed,* without "undue" experimentation. *In re Wright,* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513, 1514 n.8 (Fed, Cir. 1993); *U.S. v. Telectronic,* 857 F.2d 778, 785-86, 8 USPQ2d 1217, 1222, 1223 (Fed. Cir. 1988). Questions of enablement are questions of law based on the underlying facts in any given case. *In re Vaeck,* 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

The enablement requirement of the first paragraph of 35 U.S.C. § 112 requires that there be some reasonable correlation between the scope of the claims and the scope of enablement described in the specification, *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970), and it has been consistently held that the first paragraph of 35 U.S.C.

§ 112 requires nothing more than objective enablement. *In re Marzocchi,* 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

In meeting the enablement requirement, an application need not teach, and preferably omits, that which is well-known in the art. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (CCPA 1986). How such a teaching is set forth, whether by the use of illustrative examples or by broad descriptive terminology, is of no importance since a specification which teaches how to make and use the invention in terms which correspond in scope to the claims *must* be taken as complying with the first paragraph of 35 U.S.C. § 112 *unless* there is reason to doubt the objective truth of the statements relied upon therein for enabling support. *Marzocchi* at 439 F.2d 223, 169 USPQ at 369.

Factors to be considered in determining whether a disclosure would require "undue" experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative, skill of the routineer in the art, (7) the predictability or lack thereof in the art, and (8) the breadth of the claims. *In re Wands,* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Thus, the law as applied to a motion seeking to deny a party in an interference the benefit with respect to a count of an earlier filed application requires the moving party to direct us to the underlying facts in the earlier filed applications

which lead to the legal conclusion that the hypothetical person of ordinary skill in the art could not have made and used an embodiment within the count by following the disclosure in the earlier filed application without "undue" experimentation. Here, Falkner represents at page 10 of their motion that they do not challenge the Inglis benefit application filed on February 7, 1995 (Serial Number 08/384,963) on enablement grounds because "as of the filing of Falkner's '392 application on April 29, 1994" it is argued that "the field would have been enabled to make and use just such a vaccine (Falkner Exhibit 2009)." See page 10 of the motion.

Falkner again directs our attention to what they describe as the lack of text in the benefit applications directed to poxviruses. According to Falkner, because of the lack of "poxvirus-specific teachings" in the benefit applications the skilled routineer in the art seeking to prepare the vaccine of the count would have to "undertake undue experimentation to make and use a vaccine according to the count." See page 11 of the motion. Nevertheless, this argument merely states a conclusion.

Falkner also argues that an argument made by Inglis in Interference Number 104,363 with respect to mutations in certain genes in herpesviruses and the ability of progeny virus to infect cells constitutes an "admission" that selection of essential viral genes for inactivation "was beyond the knowledge of one of ordinary skill in the art." See the paragraph bridging pages 11 and 12 of the motion. Our reviewing court has cautioned against construing ambiguous statements or statements capable of several interpretations as "admissions". *Aktiebolaqert Karlstads Mekaniska*

Werkstad v. U.S. ITC, 217 USPQ 865 (Fed. Cir. 1983); mod'g. 217 USPQ 179. See also *Issidorides v. Ley*, 4 USPQ2d 1854 (BPAI 1987). Thus, we must carefully review the alleged "admission" and determine what, if any, relevance it may have to the issue before us.

Falkner further argues that the court's opinion in *Genentech, Inc. v. NovoNordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) mandates a finding that Inglis' benefit applications are not enabling. Specifically, Falkner urges that the court in *Genentech*, held that a specification which provided *no* detail on how to "make and use" a claimed invention could not be supplemented by asserting that all missing information on how to "make and use" the invention was well-known in the prior art and need not have been included in the disclosure.

Finally, Falkner urges that in light of the well-known differences between herpesviruses and poxviruses, Inglis' disclosure with respect to herpesviruses would not have enabled vaccines prepared from poxviruses. Falkner relies in substantial part on the testimony of Dr. Carroll in support of this argument.

In their opposition, Inglis urges that because the courts have held that test for enablement does not require an application for patent to set forth every detail on how to make and use the claimed invention, the mere fact that only herpesviruses are specifically exemplified in the benefit applications is not fatal. Inglis urges that Dr. Carroll's expressed opinion in his declaration on the ultimate legal question of whether the benefit applications do in fact satisfy

the enablement requirement of the statute based on his inadequately explained understanding of the law is not entitled to "any probative weight." See page 13 of the opposition. Inglis urges that based on the acknowledged understanding in the art of the poxvirus' structure in general and the known identity of essential genes within the genome of the virus at the time each of the benefit applications were filed, coupled with the level of skill of the routineer in this art to which the parties have stipulated, the benefit applications have not been shown to be "non-enabling" by a preponderance of the evidence as was Falkner's burden.

According to Inglis, the so-called admission made in another interference directed to different subject matter than in this proceeding is simply not relevant to the subject motion. Moreover, Inglis points out that the motion in the other proceeding was denied. As for the differences between herpesviruses and poxviruses, while admitting there are differences Inglis urges that notwithstanding those differences a skilled person in this art could have prepared vaccines from poxviruses based on the exemplification in the benefit applications using herpesviruses and without "undue" experimentation. Inglis relies, in part, on the testimony of Dr. Boursnell in support of this argument. See page 17 of the opposition and EXHIBITS 1001 and 1018.

As correctly observed by Inglis in their opposition, Falkner, as the moving party, bears the burden of proving by a preponderance of the evidence that the Inglis benefit applications fail to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph. In this instance, Falkner's burden of persuasion is no less than a primary examiner's

burden to make out a *prima facie* case of lack of enablement when rejecting an application for patent's claims under the first paragraph of 35 U.S.C. § 112, for lack of enablement. While we agree with Falkner that Inglis' benefit applications do not exemplify the preparation of a vaccine within the count, exemplification is not necessarily required for purposes of satisfying the statute and our analysis does not end there. Rather, we must look to all the underlying facts on this issue and determine if, based on all the underlying facts, Falkner has proved that the benefit application disclosures are non-enabling.

According to Falkner's motion, because there is no disclosure in any benefit application of a poxvirus lacking an essential gene and its function, no benefit application can be said to enable the subject matter of the count. Specifically, Falkner urges that it would have taken an exercise of skill outside the ordinary level of skill to prepare a poxvirus-based vaccine according to Inglis' disclosure. See paragraphs 39 and 40 through 42 of Dr. Carroll's declaration, EXHIBIT 2009. Dr. Carroll opines that the hypothetical person of ordinary skill in the art (1) would not know which poxvirus essential genes to inactivate; (2) would not know which genes to use for complimenting the essential poxvirus genes or what promoters for expressing said genes; (3) would not know which useful complimenting host cells to use; (4) would not know methods for inactivating essential genes and methods for making defective poxviruses; and (5) methods for making the complimenting cells. See paragraph 40 of EXHIBIT 2009.

While Dr. Carroll does not explain the underlying factual basis for all his conclusions, his opinions appear to be based,

in part, on his understanding that Inglis was required to include evidence in their disclosure which proved "possession of mutant poxviruses in an actual or conceptual sense" in order to satisfy the enablement requirement of the statute. See paragraphs 35, 43, 49 and 55. We agree with Inglis that Dr. Carroll's opinion on the ultimate legal issue of enablement must be supported by something more than his bare conclusion, especially where, as here, he failed to explain who explained to him the legal standard for enablement and how the legal standard was explained. See *In re Buchner,* 929 F.2d 660, 661, 18 USQP2d 1331, 1332 (Fed. Cir. 1991). Moreover, a showing of actual possession is *not* a requirement for satisfying the enablement requirement of the statute.

In their opposition, Inglis urges that there is more than ample description of preparing a vaccine from poxvirus lacking an essential gene in each of the benefit applications and it would have been a matter of simply applying the well-known technology used to prepare the vaccine from herpesvirus disclosed in the benefit applications to poxviruses as expressly suggested in the benefit applications. According to Inglis, poxvirus was well-understood and its genome well-characterized at the time the earliest benefit application was filed. Inglis urges that it was not necessary for them to include in their applications either a working example of the preparation of a vaccine from poxvirus or the specific details of how to prepare the vaccine because the routineer would have known how to prepare the vaccine based on his or her knowledge, what was known in the art about poxviruses and their use for preparing vaccines and the high level of skill. Inglis argues that the disclosure of the

preparation of vaccines from either herpesvirus or poxvirus in the benefit applications, coupled with the actual and specific exemplification of vaccines prepared from herpesviruses and what was well-known in the art with respect to the poxvirus genom and its essential genes, warrants a finding that their benefit applications are enabling in the sense of the statute for vaccines prepared from poxviruses.

We find that Falkner, the moving party, has focused almost exclusively on what allegedly is not disclosed in the Inglis benefit applications rather than addressing whether what *is* disclosed and how what *is* disclosed would have been considered as it would have been by the hypothetical person of ordinary skill in the art when the benefit applications were filed. We note that the parties have stipulated that the person of ordinary skill in the art is defined as:

> . . . a molecular biologist, having an advanced scientific degree, and having about 5-10 years experience with creating recombinant virus. The person is familiar with the scientific literature describing poxvirus, the use of poxvirus as a vector for expression or heterologous genes, and the manipulation of poxvirus to create attenuated or mutated poxvirus. The person would have the needed technical skill to practice the experimentation described in the scientific literature relating to recombinant virus, including poxvirus.

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We agree with the parties' stipulation, as reflected in the voluminous prior art and reference material cited in the record, that the routineer in this art is highly skilled and extremely familiar with poxviruses and their use in the preparation of vaccines. In our view, Falkner's motion has not shown that this routineer could not have practiced the invention disclosed in the Inglis benefit applications without "undue" experimentation.

Thus, EXHIBIT 2016, the benefit application with the earliest filing date, discloses "an attenuated virus for use as a vaccine, in which a viral gene encoding a protein which is essential for the replication of said virus has been deleted or inactivated." See page 4, line 26 through page 5, line 3. At page 6, lines 13 through 16 of EXHIBIT 2016, it is disclosed that the virus may be a poxvirus, for example, vaccinia virus. At page 8, lines 10 through 12, it is disclosed that any virus in which one or more essential genes can be identified and deleted or inactivated may be used to prepare the vaccine. On pages 9 and 10, criteria for selecting essential genes are set forth. In lines 11 through 16, it is disclosed that the deletion or inactivation of the gene must produce a non-functional gene. Complementation of the gene which has had an essential gene either inactivated or deleted is also disclosed. See page 7, lines 3 through 11. There is extensive disclosure of the selection of an essential gene, its deletion or inactivation and the production of a mutated virus with said deleted or inactivated essential gene, albeit for herpesvirus. See pages 14 through 21. Falkner has not proved that the routineer could not have practiced the subject matter of the count based on this disclosure and what was known and understood by the routineer in this art without "undue" experimentation.

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We observe that the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be "undue" in this art. Indeed, it appears from the art in the voluminous record that complex laboratory techniques requiring great expenditures of time and effort were ordinary in the field of vaccine preparation.

Falkner's argument that the court's decision in *Genentech, Inc. v. Novo Nordisk, A/S,* 108 F.3d 1361, 42 USPQ2d 1001 (Fed. Cir. 1997) supports their argument that Inglis' benefit applications are non-enabling is unavailing. In our view, Falkner has fallen into the practice of first presenting decisions from our reviewing courts generally related to the question before us but in which decisions the facts differ substantially from the facts before us and then crafting a rule of law from these cases said to be applicable to all cases regardless of the facts. As one of the predecessors to our reviewing court cautioned in *In re Edwards,* 568 F.2d 1349, 1354, 196 USPQ 463, 469 (CCPA 1978):

> suffice it to say that each case must be decided on its own facts, see, e.g., In re Driscoll, *supra,* and that precedential value of prior cases is, therefore, extremely limited.

In *Genentech,* the case cited by Falkner, the court specifically observed that the invention claimed in the involved application in litigation was *not* disclosed in the first filed application which was filed some 15 years before the involved patent was filed and which disclosure was identical

to the disclosure of the application in litigation. Indeed, the court observed in its opinion that Genentech was attempting to claim in the subsequently filed application "the unresolved problem that the '980 patent overcame." 108 F.3d at 1366, 42 USPQ2d at 1005.

Falkner has argued that because of the well-known differences between herpesviruses and poxviruses, the benefit applications' disclosure of the preparation of vaccines from herpesviruses would not have enabled the routineer to make vaccines from poxviruses. However, this is little more than mere attorney argument unsupported by any facts. Rather, we find that because the differences between the two viruses would have been well-known and well-understood by the skilled person in the art, the preparation of a vaccine from poxvirus based on the exemplification of a vaccine prepared from herpesvirus would have been rendered more facile. Additionally, the skilled person in the art would have also known about vaccinia virus, a particular poxvirus, and its usefulness in the preparation of vaccines, in general. Coupled with Inglis' disclosure of preparing a vaccine from an attenuated form of herpesvirus, Falkner has failed to address and failed to provide adequate evidence why the skilled routineer would have been unable to make a vaccine within either embodiment of the count based on what is disclosed in the benefit applications.

We have not overlooked Dr. Carroll's testimony to the contrary on this issue but find his testimony lacking in setting forth or explaining the underlying factual basis for his conclusions and observations. Even the opinion of an expert must be supported by specific reference to the underlying

facts which form the basis of his or her opinion. *Cable Electric Products, Inc. v. Genmark, Inc..*, 770 F.2d 1015, 1025, 226 USPQ 881, 887 (Fed. Cir. 1985); *In re Grunwell*, 609 F.2d 486, 491, 203 USPQ 1055, 1059 (CCPA 1979). **FRE** 702(1). It is not sufficient to merely explain that the expert (declarant) has read numerous volumes of learned treatises and relevant publications and that these treatises and publications, in general, form the basis for all of his or her opinions.

Accordingly, for all the above stated reasons, Falkner has failed to prove Inglis' benefit applications are non-enabling and, therefore, Falkner's motion to deny Inglis the benefit of the earlier filed applications accorded them when this interference was declared is **DENIED.**

FALKNER'S PRELIMINARY MOTION 4

Falkner moves pursuant to 37 CFR § 1.633(c)(4) to redefine this interference and designate Falkner's claims 6, 8, 9, 16, 17 and 19 of their involved patent as claims not corresponding to the count.

Claims 6, 8, 9 of Falkner's involved patent depend from independent claim 1. Independent claim 1 of Falkner's involved patent forms the first alternative of the bifurcated count of this interference and is directed to a vaccine. Claims 16, 17 and 19 depend from Inglis' independent claim 10. Independent claim 10 of Falkner's involved patent is directed to a method for producing a vaccine by "providing" a defective poxvirus as in claim 1, infecting a complementing cell line with said defective poxvirus and harvesting said

defective virus. All Falkner's involved patent claims were designated as corresponding to the count when this interference was declared.

A motion under 37 CFR § 1.633(c)(4) must (1) identify the claim(s) sought to be designated as not corresponding to the count and identify the count and (2) show that the claims do not define the same patentable invention as any other claim whose designation in the notice declaring the interference as corresponding to the count the party does not dispute. See 37 CFR §§ 1.637(c) (4) (1) and 1.637(c) (4) (ii) . Thus, it was Falkner's burden to prove that claims 6, 8, 9, 16, 17 and 19 do not define the "same patentable invention" as any of claims 1 through 5, 7, 10 through 15 and 18 of their involved patent *and* any of Inglis' claims 9, 10, 29 and 30 designated as corresponding to the count. This Falkner has not done.

The test for determining whether claims are directed to the "same patentable invention" under the so-called "600" interference rules is a two-way test. *Eli Lilly & Co. v. Board of Regents of the University of Washington*, 334 F.3d 1264, 1267-69, 67 USPQ2d 1161, 1164 (Fed. Cir. 2003).

The Falkner motion does not address the question of the separate patentability of claims 6, 8 and 9 of their involved patent from claim 1 of their involved patent. Claim 1 of their involved patent recites that the defective poxvirus is one comprising "a DNA polynucleotide encoding an antigen and said DNA polynucleotide is under transcriptional control of a promoter." Claims 6, 8 and 9 which depend on claim 1 specify the antigen of claim 1. Thus, because a species ordinarily "anticipates" a genus, claims 6, 8 and 9 anticipate claim 1.

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Whether a genus renders a species within the genus unpatentable is another question and the answer depends on the facts in each particular case. Where a genus is relatively small, the disclosure in the prior art of the small genus may "anticipate" a species within the small genus. Or there may be sufficient guidance in the nature of a pattern of preferences in the disclosure including the small genus such that selection of the species is considered to be described by the small genus. *In re Schaumann*, 572 F.2d 312, 315-316, 197 USPQ 5, 8-9 (CCPA 1978). Nevertheless, a species within a genus may still be patentable if that species has properties so distinct from the other members of the genus that the species could be said to have properties "unexpected" from the rest of the genus. Thus, it has been held that a genus does not necessarily render obvious all species within the genus because individual species within the genus may have "unexpectedly" different properties from all other members of the genus. *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994); *In re* Jones, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992). Falkner's motion, however, does not provide a basis for adopting or rejecting any of these approaches.

For all the above reasons Falkner has not proved it is entitled to the relief it requested, therefore, the motion is **DENIED**.

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FALKNER PRELIMINARY MOTION 1

Falkner moves for judgment against Inglis under 37 CFR § 1.633(a) on the grounds that Inglis' claims 9, 10, 29 and 30 designated as corresponding to the count "are not patentable to Inglis due to a lack of written description" in Inglis' involved application. On page 4 of the motion, Falkner specifically recites that:

> Falkner does not attack the Inglis '040 claims on enablement grounds because the field would have been enabled by Falkner's own earlier-filed application, U.S. Serial No. 08/235,392 (Falkner EXHIBIT 2019) filed April 29, 1994.

Accordingly, *no* issue of "enablement" under the first paragraph of Section 112 is raised by Falkner's motion.

According to Falkner, because Inglis' claims designated as corresponding to the count require a "mutant virus" which is "a pox virus" and because the "bulk of the Inglis '040 application concerns mutant herpesviruses, not mutant poxviruses" (see page 7 of the motion), Inglis' involved application cannot be considered to show possession of "a vaccine comprising mutant poxvirus." *Id.* Falkner relies in part on the declaration testimony of Dr. Carroll (Falkner EXHIBIT 2009) in support of their arguments.

Nevertheless, Dr. Carroll's testimony is overwhelmingly devoted to the issue of whether or not a person of ordinary skill in the art could make and use the invention disclosed by Inglis in their involved application. As we have noted

above, Falkner has specifically stated on page 4 of their motion that they do *not* attack the Inglis claims designated as corresponding to the count on enablement grounds. Thus, Dr. Carroll's testimony: in paragraph 25 of his declaration that he is unable to find "discussion . . . of the actual creation of the recited" mutant poxvirus; in paragraph 26 about his own understanding of the enablement requirement as explained to him by unnamed persons; in paragraph 29 about how to make and use the invention described in Inglis' involved application; in paragraph 30 concerning the issues a person of ordinary skill would be confronted with when attempting "to make the claimed vaccine according to the Inglis '040 application"; in paragraph 32[5]; and, again in paragraph 32 opining that the skilled routineer would be required to turn to "other sources" to make a vaccine as claimed in Inglis' involved application, is not relevant to the issue specifically presented to us by Falkner for decision in their motion.

The remainder of Dr. Carroll's declaration testimony is directed to Inglis' benefit applications and, accordingly, is not relevant to the issue before us. Specifically, a motion for judgment can only be granted with respect to a party's claims designated as corresponding to the count which may only be found in a party's involved application. Compliance with the first paragraph of the statute is determined based on the disclosure of the application whose disclosure is being questioned *not* the disclosures of any parent applications. *Reiffen v. Microsoft,* 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000) (disclosure in parent and grandparent

5. We observe that there is no paragraph 31 in Dr. Carroll's declaration.

applications' specification irrelevant to patentability under 35 U.S.C. § 112, first paragraph, of the claims of patent in issue).

Nothing in Falkner's motion or Dr. Carroll's declaration testimony adequately addresses what the above-noted disclosures would have meant to a person of ordinary skill in the art at the time Inglis' involved application was filed. Nor does Falkner's motion apply the above-noted disclosures to the language of Inglis' *claims*, designated as corresponding to the count. The absence of such analysis is fatal to granting Falkner's motion. After all, the essence of resolving the question of whether there is a sufficient "written description" of Inglis' invention requires analyzing Inglis' claims! The reference in the first paragraph of Section 112 to "the invention" is, of course, a reference to the ***claimed*** invention. Accordingly, the motion is **DENIED**.

FALKNER PRELIMINARY MOTION 3

Falkner moves for judgment against Inglis on the grounds that all Inglis' claims designated as corresponding to the count, claims 9, 10, 29 and 30, are unpatentable under 35 U.S.C. §§ 102 and 103.

The relief which Falkner requests is founded on the premise that because Falkner urges that Inglis is not entitled to the benefit of *any*, of their earlier filed applications under 35 U.S.C. §§ 119, 120 and 365, the Falkner patent, U.S. Patent Number 5,766,882 (the '882 patent), is patent-defeating "prior art." According to Falkner's motion, none of the earlier filed Inglis applications "comply with the

written description and enablement requirements" of the statute and, therefore, one of Falkner's benefit applications which issued U.S. Patent Number 5,766,882 in March 1995, is "prior art" against the claims of Inglis' involved application. As the moving party, Falkner bears the burden of proof.

As we observed above, in order to establish that a party is not entitled to the benefit of the filing date of an earlier U.S. application for patent (35 U.S.C. § 120) or an application for patent filed in a foreign country (35 U.S.C. §§ 119, 365), a party must demonstrate lack of compliance under 35 U.S.C. § 112, first paragraph, in the benefit applications for the *full scope of what is claimed in the application seeking to obtain benefit*. Although what Falkner must prove here to have its motion granted is different from what it was required to prove to have its motion under 37 CFR § 1.633(g) granted, Falkner's arguments in this motion are essentially the same as in their motion to deny benefit. Specifically, Falkner argues that because the benefit applications exemplify the preparation of a vaccine from herpesvirus and not poxviruses, and because there is no identification of any essential region or gene in poxviruses or how to prepare complementing host cells for defective poxviruses or methods for inactivating essential genes in poxviruses, none of the benefit applications can be said to either describe or enable the subject matter claimed by Inglis in its involved application in this interference.

While Falkner recognizes the proper legal standard for measuring whether an application satisfies 35 U.S.C. §§ 119, 120 and § 365, that is, whether the applications for which

benefit of the earlier filed applications is sought "supports the claims in question in a manner compliant with the first paragraph of 35 U.S.C. § 112", there is ***no*** discussion let alone analysis of the involved Inglis application claims designated as corresponding to the count *vis-a-vis* the disclosure in each benefit application. We recognize that at pages 13 through 15 of the motion Falkner "reads" the limitations of Inglis' claims on the disclosure of Falkner's '882 patent but that analysis does not address what is disclosed in the benefit applications or what is claimed in the involved Inglis application.

We find, for example, that with respect to Inglis' claim 9 designated as corresponding to the count, Inglis' benefit application Serial Number 08/384,963 describes a "vaccine" comprising a virus and one or more excipients and/or adjuvants for use in the therapeutic or prophylactic treatment of disease. See page 5, lines 18 through page 6, line 17 of EXHIBIT 2013. The virus used to prepare the vaccine is a mutant virus in which a viral gene essential for the production of infectious virus has been deactivated or deleted. See page 5, lines 9 through 16 of EXHIBIT 2013. The virus may be an orthopox virus, specifically, vaccinia virus. See page 6, line 19 through page 7, line 4 of EXHIBIT 2013. The mutant virus having a selected gene deactivated or deleted is able to produce more viral protein from the replicated genetic material but is not infectious. See page 7, lines 11 through 20 of EXHIBIT 2013. A complementing cell which provides the virus with the product of the gene which has been deleted is also provided. See page 7, line 21 through page 8, line 20 of Exhibit 2013. Criteria for selecting the essential gene to be deactivated or deleted are specifically set forth. See page

8, line 21 through page 9, line 12 and page 10 line 11 through page 12, line 8. Preparation of the vaccine is exemplified with herpesvirus at pages 16 through 37 of EXHIBIT 2013.

The Falkner motion does not explain why the person of ordinary skill in the art would have been unable to practice without undue experimentation the invention claimed by Inglis by following said disclosure but using poxvirus instead of herpesvirus. It does not appear open to factual dispute that the poxviruses in general and vaccinia virus in particular were well-characterized at the time the Inglis benefit applications were filed. Coupled with the stipulated level of skill of the routineer in this art at the time the Inglis applications were filed, we find that Falkner has simply failed to carry its burden of persuasion in their motion.

Accordingly, because Falkner has failed to prove that Inglis is not entitled to the benefit of its earlier filed applications, the Falkner '882 patent is *not* prior art with respect to Inglis' involved application. The requested relief is, therefore, **DENIED**.

INGLIS' PRELIMINARY MOTIONS

INGLIS PRELIMINARY MOTION I

Inglis moves for judgment under 37 CFR § 1.633(a) against Falkner on the grounds that all Falkner's claims designated as corresponding to the count are unpatentable, either under 35 U.S.C. § 102 and under 35 U.S.C. § 103. Specifically, Inglis urges that Falkner's claims 1, 4, 5, 7, 10, 12, 13, 15 and 18 designated as corresponding to the count

are unpatentable under 35 U.S.C. § 102 on the grounds they are "anticipated" by one of Inglis' benefit applications, **WO** 92/05263, published on April 2, 1992. Further, Inglis also urges that the very same claims which are urged to be "anticipated" by **WO** 92/05263 are unpatentable under 35 U.S.C. § 103 from the disclosure of **WO** 92/05263 alone or considered with other prior art.

The literal language of the statute speaks in terms of description, not "anticipation." The term "anticipation" is a term of art meaning "the disclosure in the prior art of a thing substantially identical with the claimed invention." *Schaumann* at 572 F.2d at 317, 197 USPQ at 10. Whether a prior art reference "anticipates" a claimed invention and thus renders it unpatentable is a question of fact. *Ralston Purina Co. v. Far-Mar-Co., Inc.* 772 F.2d 1570, 1574, 227 USPQ 177, 179 (Fed. Cir. 1985). The determination entails a two-step process. First, the claim in question must be properly construed. Second, it must be determined if each and every element of the properly construed claim is "described" by the prior art reference.

A reference may still be said to describe a claimed invention even if a limitation is not expressly described if the missing limitation would have been inherent in the thing described. *Whether* a claim limitation is inherent in a reference is also a question of fact, *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Stated another way, when a reference relied on under § 102 is missing a claimed element it may still be said to "anticipate" the claimed subject matter if it can be shown that the reference *necessarily* describes the

missing element. The showing may be made by use of extrinsic evidence. The evidence must make it *absolutely* clear that the missing element is *necessarily* present in the thing described by the reference *and* would have been so recognized by a person of ordinary skill in the art. As one of the predecessors to our reviewing court held in *In re Oelrich,* 666 F.2d 578, 581, 212 USPQ 323, 326, quoting from *Hansgir v. Kemmer,* 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939):

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. [Citations omitted.] If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

It is based on this understanding of the law of "anticipation" that we consider Inglis' motion for judgment.

As the moving party Inglis bears the burden of proving that the proffered reference describes what Falkner claims in claims 1, 4, 5, 7, 10, 12, 13, 15 and 18 of its involved application. Inglis refers in its motion to Fact 3 in support of the relief requested. See page 8 of the motion. Fact 3 states a conclusion that claims 1, 4, 5, 7, 10, 12, 13, 15 and 18 of Falkner's involved patent are disclosed in the reference and incorporates by reference in Fact 3 EXHIBIT 1003. EXHIBIT

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1003 is the claim chart alleged to show each element of Falkner's claims designated as corresponding to the count and also allegedly show where the disclosure of each element of the claims may (or may not) be found in **WO** 92/05263. Recognizing that in order for a reference to be anticipatory, the reference relied on must be enabling, Inglis argues that based on: the level of skill in the art; EXHIBIT 1001 (Dr. Boursnell's declaration); and, various prior art the **WO** 92/05263 reference includes a description of Falkner's claimed invention. Inglis urges that the description would have enabled the routineer to prepare the vaccines described therein and the vaccines described therein "anticipate" Falkner's claimed vaccines.

In its opposition, Falkner urges that the motion should be dismissed on procedural grounds. Falkner also argues that because the **WO** 92/05263 is directed to vaccines prepared from herpes viruses not poxviruses, it cannot be *said* to "anticipate" Falkner's claims. Falkner argues that not only does the reference fail to describe every element of Falkner's claims designated as corresponding to the count but also that the disclosure of the reference is so deficient as to preclude the routineer from preparing a vaccine as claimed by Falkner based on the disclosure in the reference without undue experimentation.

On the first page of EXHIBIT 1003, in the analysis of claim 1 and under the element heading "1.5 and said DNA polynucleotide is under the transcriptional control of a promoter", Inglis directs our attention to the disclosure found at page 14 lines 13 and 14 of **WO**92/05263 for a description, in the sense of § 102, of said element or limitation.

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Nevertheless, the disclosure at page 14 is directed to the ability of vaccinia virus, a particular, well-known poxvirus, to "carry and express genes from various pathogens" and the use of a vaccinia virus modified to carry and express genes from various pathogens as an effective vaccine in animals. Inglis has failed to explain why we should construe the referenced disclosure as being directed to a defective poxvirus lacking a function imparted by an essential region of the parental poxvirus. Moreover, the remainder of the context from the cited portion of the reference discusses the "reluctance to use an unmodified vaccinia virus on a large scale in humans." We do not understand that an "unmodified vaccinia virus" would be understood to mean a "defective poxvirus that lacks a function imparted by an essential region of its parental poxvirus."

Thus, Inglis has failed to provide a sufficient factual basis on which we could find Falkner's claims are "anticipated" by the proffered reference. Accordingly, it is unnecessary for us to reach the issue of whether the proffered reference is "enabling" or any other of the various arguments raised by the parties in their respective oppositions and replies.

Inglis also urges that all Falkner's claims designated as corresponding to the count are unpatentable because the subject matter therein claimed would have been obvious from **WO** 92/05263 alone or, with respect to some claims, from **WO** 92/05263 considered with "prior art analogous to **WO** 92/05263." We hold that the motion does not adequately make out a *prima facie* case of obviousness.

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The Supreme Court in *Graham v. John Deere,* 383 U.S. 1, 148 USPQ 459 (1966), its seminal decision on 35 U.S.C. § 103, recognized that obviousness was a question of law but observed that the legal question lent itself to "several factual inquiries." Specifically, at 383 U.S. 17, 148 USPQ 467, the Supreme Court found that:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Accordingly, the subject motion should have included: a determination of the scope and content of *all* the prior art on which Inglis relied; an analysis of *every* claim against which judgment was sought and an analysis of the differences between the prior art and the properly construed claims; and, a determination of the level of skill in the art. Where movant relied on more than a single prior art reference, evidence supporting why the skilled routineer would have been motivated to make the proffered combination of references should have been supplied. Thus, we agree with Falkner's argument from its opposition that Inglis' motion lacks both the requisite factual inquiries set forth in *Deere,* and the application of those facts as they apply to the law of obviousness.

For all the above reasons the motion is **DENIED**.

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INGLIS PRELIMINARY MOTION 2

At oral hearing, counsel for Inglis was asked if the relief requested in this motion, the addition of certain claims to Inglis' involved application in this proceeding to be designated as corresponding to the count, was conditional on the grant of Falkner's Preliminary Motion 3. Counsel for Inglis explained that if Falkner's motion for judgment were denied it would be unnecessary for us to reach Inlgis' Preliminary Motion 2. See Paper Number 58, **"FALKNER'S SUBMISSION OF TRANSCRIPT"**, page 34, lines 2 through 14.

Stated another way, counsel for Inglis represented that its Preliminary Motion 2 was contingent upon the grant of Falkner Preliminary Motion 3. Accordingly since Inglis preliminary Motion 2 is contingent upon an event which has *not* occurred, Inglis' motion is **DISMISSED**.

FALKNER'S MOTION TO SUPPRESS

The motion is **DISMISSED**. As we observed above, Judge Lee has previously ruled that the motion was unauthorized but, nevertheless, provided Falkner an opportunity to argue why the motion should be granted at the oral argument. At the oral argument, Falkner's counsel was specifically asked if he was aware of Judge Lee's order and that he was provided up to five minutes of time to argue in support of granting the motion. Counsel for Falkner represented he was aware of Judge Lee's order and that he was aware he was provided up to five minutes of argument at the oral hearing to explain why the motion should be

granted. See page 4, line 18 through page 5, line 10 of Paper Number 58. Counsel for Falkner, however, did not make any argument in the time provided for why the motion should be granted. Accordingly, we shall not disturb Judge Lee's order. The motion stands **DISMISSED**.

PRIORITY OF INVENTION

All the parties' preliminary motions and motions to suppress have now been decided. Neither party has moved to change or substitute the count so the count remains as set forth in the papers declaring this interference. By virtue of their respective filing dates, Falkner remains the junior party and Inglis remains the senior party.

Only the junior party Falkner has filed a preliminary statement[6]. Only the junior party filed and served a notice of filing a preliminary statement. Inglis is, thus, a party which did not file a preliminary statement and is restricted to its effective filing date of September 25, 1990, the date it was accorded of its earliest filed benefit application.

In an order issued by Judge Lee on March 3, 2004, the parties were required to file but not serve by Time Period 1 their respective preliminary statements and to file and serve the notice of filing their respective preliminary statements within Time Period 1. In the same order, the parties were advised to serve a copy within 1 (one) week after Time Period 1 their preliminary statement on any "opponent who served

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6. Preliminary statements under the "old" rules are now known as "priority statements." See 37 CFR § 41.204.

a notice under 37 C.F.R. § 1.621(b)." By stipulation of the parties, Time Period 1 was extended to June 11, 2004. See Paper Numbers 18 and 21.

Pursuant to 37 CFR § 1.627(b), Falkner's preliminary statement is now open on the record. Falkner is now ordered to serve a copy of its preliminary statement on Inglis. Falkner's preliminary statement alleges as the earliest date of invention April 27, 1994, the date on which a conception and the beginning of the exercise of reasonable diligence began. Falkner also alleges a constructive reduction to practice on April 29, 1994, the day its first filed benefit application was filed. Based on the senior party's effective filing date of September 25, 1990, Falkner's alleged dates are ineffective to overcome the presumption that Inglis was the first inventor of the subject matter of the count.

Accordingly, it is:

ORDERED that judgment as to the subject matter of the count shall be entered against the junior party Falko-Günter Falkner, George Holzer and Friedrich Dorner in a separate paper on even date with this decision;

FURTHER ORDERED that judgment as to the subject matter of the count shall be awarded to Stephen C. Inglis, Michael E.G. Boursnell and Anthony C. Minson, the senior party.

Appendix B

REQUESTS FOR REHEARING

Although this decision was rendered based on the parties' various preliminary motions, the parties are advised that because we are entering judgment against the junior party as to Count 1, the sole count in this proceeding, on priority grounds any request for rehearing of this decision on motions shall be filed in accordance with the provisions of 41 CFR § 1.127(d).

We remind the parties that any request for rehearing must "specifically identify" all matters we allegedly "misapprehended or overlooked" in rendering our decision. See 41 CFR § 41.127(d), second sentence. Oppositions to any request for rehearing are not authorized unless requested by the Board. The filing of a request for reconsideration should not be considered by the parties as an opportunity to prove elements of their case which they neglected to prove in their motions.

BOARD OF PATENT APPEALS
AND INTERFERENCES

s/ Andrew H. Metz
Andrew H. Metz
Administrative Patent Judge

s/ Richard E. Schafer
Richard E. Schafer
Administrative Patent Judge

s/ Richard Torczon
Richard Torczon
Administrative Patent Judge

Appendix B

Paper No. 60

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEAL AND INTERFERENCES

FALKO-GUNTER FALKNER, GEORG HOLZER AND FRIEDRICH DORNER URQHART

Junior Party[1]

v.

STEPHEN C. INGLIS, MICHAEL E.G. BOURSNELL, ANTHONY C. MINSON

Senior Party[2]

---

1. Application 08/802,985, filed February 21, 1997, now U.S. Patent Number 5,770,212, issued on June 23, 1998. Said patent accorded benefit of: U.S. Application Serial Number 08/616,133, filed December 22, 1999, and now U.S. Patent Number 5,766,882, issued on June 16, 1998; U.S. Application Serial Number 08/235,392, filed on April 24, 1994, and now abandoned. Assigned to Immuno Aktiengesellschaft, Austria. Hereinafter, the junior party is referred to as "Falkner."

2. Application Serial Number 08/459,040, filed June 2, 1995. Accorded benefit of: U.S. Application Serial Number 08/384,963, filed February 7, 1995, now U.S. Patent Number 5,665,362, issued September 9, 1997; U.S. Application Serial Number 08/030,373, filed

(Cont'd)

Appendix B

Patent Interference No. 105,187

JUDGMENT – RULE 41.204 (a)(3)

Before Metz, Schafer and Torczon, *Administrative Patent Judges.* Metz, *Administrative Patent* Judge

We found in our **"DECISION ON PRELIMINARY MOTIONS"** filed on even date with this judgment that the junior party's preliminary statement failed to overcome the earliest filing date accorded the senior party in this interference. Accordingly, it is now appropriate to enter judgment against the junior party. It is, therefore,

ORDERED that judgment as to the subject matter of Count 1, the sole count in this interference, is entered against Falko-Gunter Falkner, George Holzer and Friedrich Dorner, the junior party, on the grounds that the junior party was not the first inventor of the subject matter of Count 1.

ORDERED that judgment as to the subject matter of Count 1, the sole count in this interference, is awarded to Stephen C. Inglis, Michael E.G. Boursnell and Anthony C. Minson, the senior party, on the grounds that the senior party is the first inventor of the subject matter of Count 1.

(Cont'd)

May 20, 1993, and now abandoned; PCT/GB91/01632, filed September 23, 1991, published as WO 92/05263; GB 9104903.1, filed March 8, 1991; and GB 9020799.4, filed September 25, 1990. Assigned to Cantab Pharmaceuticals Research Limited, UK. Hereinafter the senior party is referred to as "Inglis."

Appendix B

FURTHER ORDERED that Falko-Günter Falkner, George Holzer and Friedrich Dorner, the junior party, are not entitled to claims 1 through 19 of their involved patent in this interference, U.S. Patent Number 5,770,212, and designated as corresponding to Count 1.

FURTHER ORDERED that, based on this record, Stephen C. Inglis, Michael E.G. Boursnell and Anthony C. Minson, the senior party, are entitled to claims 9, 10, 29 and 30 of their involved U.S. application for patent, Serial Number 08/459,040, and designated as corresponding to Count 1.

FURTHER ORDERED that a copy of this judgment be filed in the respective involved applications and patent of the parties.

BOARD OF PATENT APPEALS
AND INTERFERENCES

s/ Andrew H. Metz
Andrew H. Metz
Administrative Patent Judge

s/ Richard E. Schafer
Richard E. Schafer
Administrative Patent Judge

s/ Richard Torczon
Richard Torczon
Administrative Patent Judge

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING AND FOR REHEARING EN BANC FILED AUGUST 24, 2006

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

05-1324
(Interference No. 105,187)

FALKO-GUNTER FALKNER, GEORG HOLZER, and FRIEDRICH DORNER,

Appellants,

v.

STEPHEN C. INGLIS, MICHAEL E.G. BOURSNELL, and ANTHONY C. MINSON,

Appellees.

ORDER

A combined petition for panel rehearing and for rehearing en bane having been filed by the Appellant, and a response thereto having been invited by the court and filed by the Appellee, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en bane and response having been referred to the circuit judges who are in regular active service,

Appendix C

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on August 31, 2006.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 08/24/2006

No. 06-693

Supreme Court, U.S.
FILED
DEC 18 2006
OFFICE OF THE CLERK

In The Supreme Court of the United States

FALKO-GUNTER FALKNER, GEORG HOLZER and FRIEDRICH DORNER,

Petitioners,

v.

STEPHEN C. INGLIS, *et al.*,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Petition presents any question appropriate for grant of certiorari where the alleged errors relate to disputed factual issues on which Respondent prevailed in the proceedings below?

STATEMENT OF PARTIES AND CORPORATE INTEREST

The parties who appeared in the proceeding below are Falko-Gunter Falkner, Georg Holzer and Friedrich Dorner ("Petitioner") and Stephen C. Inglis, Michael E.G. Boursnell, and Anthony C. Minson ("Respondent").

The real party in interest for Stephen C. Inglis et al. (Respondent) is Xenova Research Limited, formerly Cantab Pharmaceuticals Research Ltd. All parent companies and publicly held companies which own 10% or more of the stock of the real party in interest are: Xenova Group Ltd.

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OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

SUMMARY OF THE ARGUMENT

The Petition explains no connection between a conflict among the judges of the Court of Appeals for the Federal Circuit ("Federal Circuit") and the facts of the present case. Petitioner suggests an intra-Federal Circuit controversy concerning whether the "written description" requirement of 35 U.S.C. § 112 is separate from the "enablement" requirement of 35 U.S.C. § 112. The Federal Circuit's opinion in this case, however, does not indicate any relation between this case and such a controversy. The Federal Circuit's analysis addressed enablement *and* written description, applying a correct legal analysis to both issues.

Identifying no legal error, Petitioner reargues factual matters to allege that Inglis' disclosure is not sufficient to satisfy the enablement and written description requirements. These arguments raise no compelling issues for certiorari, however, since the sufficiency of a party's patent application disclosure, for purposes of both written description and enablement, is based on factual determinations. The disputed factual issues were resolved against Petitioner based on the evidence presented at the agency level, before the Board of Patent Appeals and Interferences at the U.S. Patent and Trademark Office ("Board").

As explained in this Opposition, Petitioner's arguments asserting the insufficiency of Inglis'

disclosures are contrary to the weight of evidence developed in the record. Petitioner is dissatisfied with the Board's factual findings, and with the weighing of the evidence in this case, but the Board's factual findings are fully supported by the record and were found to be free of error by the Federal Circuit.

For these reasons, the Petition presents no compelling issues for review and the request for a writ of certiorari should be denied.

ARGUMENT

1. This Case is Unconnected to a Dispute within the Federal Circuit, and the Petition Presents no other Compelling Reasons for Grant of Certiorari

On pages 5 of the Petition, it is asserted that certiorari should be granted since a conflict exists among some of the judges of the Federal Circuit which "concerns whether there exists a separate written description requirement in the patent laws ... beyond enabling an invention ..." See also pp. 17 and 19 of the Petition. In response, Respondent disagrees that the indicated conflict has any relevance to this case. The opinion of the Federal Circuit panel addressed the sufficiency of the Inglis disclosures from the standpoint of *both* enablement (App. 14a-15a) and written description (App. 15a–

21a).[1] The Federal Circuit opinion contains no discussion of whether the written description requirement is separate from the enablement requirement. Indeed, Petitioner never raised any argument based on the separateness of those requirements before either the Board or the Federal Circuit.[2]

There was no dissent from the Federal Circuit panel opinion. App. 1a-21a. Moreover, Petitioner raised the same objections which are raised in the Petition in a "Combined Petition for Rehearing and Petition for Rehearing En Banc by Appellant Falkner" filed with the Federal Circuit on June 26, 2006. The Federal Circuit summarily denied all aspects of the relief requested in that Petition, with no written opinion and no judges dissenting from the denial of *en banc* review, by Order of August 24, 2006. It is reasonable to conclude that the Federal

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[1] Respondent uses the same abbreviations to refer to the Appendix to the Petition ("App. __a") and the Joint Appendix ("A __") record used by Petitioner. See footnote 6 on page 7 of the Petition.

[2] Page 2 of the Petition asserts conflict within the Federal Circuit on the basis of "two competing ideologies" but does not clearly spell out what those two alleged competing ideologies are. Petitioner suggests that the "ideology" which prevailed in this case requires only the "thinnest" disclosure. The competing ideology is not specified. Nor is it explained how these "competing ideologies" – whatever they are - have any relation to whether the enablement and written description requirements are separate. The Petition argument as a whole, therefore, does not clearly articulate the alleged "conflict" within the Federal Circuit, nor how this case is related to the alleged conflict.

Circuit saw none of the significance or urgency to this case which is asserted in the Petition.

The dissents from other Federal Circuit decisions, cited on pages 2, 17-18 and 20 of the Petition, have no demonstrated relevance to the facts of this case.[3] One of the dissents cited on page 18 of the Petition is by Judge Gajarsa, yet, Judge Gajarsa authored the Federal Circuit opinion in this case, further illustrating the absence of a connection between this case and any intra-Federal Circuit dispute.

In place of any compelling legal issue, the Petition presents reargument of the same allegations made below against the sufficiency of Inglis' disclosures.[4] As explained herein, these contentions deal with disputed factual issues. These arguments have been rejected by the Board (based on the contested evidentiary record and Petitioner's failure to prove its allegations) and rejected by the Federal Circuit (based on finding substantial evidence support for the Board's factual findings). Moreover,

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[3] On pages 20-21 of the Petition, Petitioner cites the dissent from the denial of *en banc* review by the Federal Circuit in *University of Rochester v. G.D. Searle and Company*, 375 F.3d 1303 (Fed. Cir. 2004). The citation provided by Petitioner is not complete since it omits an indication that certiorari was denied in that case, at 543 U.S. 1015, 125 S. Ct. 629 (2004).

[4] The "Inglis disclosures" refers to the Inglis priority applications (which Falkner challenged before the Board on both written description and enablement grounds) and the Inglis '040 application involved in the interference (which Falkner challenged before the Board only on written description grounds).

the decision reached below is based on a correct application of the law relating to written description and enablement. There was no misapplication of law requiring correction by this Court.

2. The Content of Inglis' Patent Applications is Incorrectly Characterized Throughout the Petition

The Petition describes the Inglis patent applications as containing only a two-sentence disclosure relevant to poxvirus embodiments. See, e.g. Petition at page 6, lines 3-6; page 7, 2d full paragraph; page 13, lines 19 and 27; page 14, lines 2 and 16-20; page 22, lines 2-3; page 30, lines 7-13. In response, this characterization of Inglis' disclosures is incorrect. The Inglis applications describe the subject invention broadly as being applicable to vaccines based on different viruses. The invention is then exemplified more specifically by reference to herpesvirus and poxvirus embodiments. As the Federal Circuit explained, the Inglis applications contain generic (general) disclosure, followed by detailed working examples which exemplify the invention by reference to herpesvirus embodiments, and three passages (not two sentences) which describe that the invention includes poxvirus embodiments. App. 11a-15a. Petitioner's suggestion that the "generic" disclosure and herpesvirus exemplification is irrelevant to practicing poxvirus embodiments is contrary to the factual findings made below. For example, the Board found that Inglis' disclosure for identifying an essential viral gene was "extensive" (App. 48a) and specifically

found that the herpesvirus embodiment working examples provided by Inglis would render making a poxvirus embodiment "more facile" (App. 50a).

3. The Decision Finding Enablement of the Inglis Priority Applications was Based on Application of the Correct Legal Standard of Enablement and was Amply Supported by the Evidence of Record

The Petition argument focuses on the allegedly insufficient *quantity* of disclosure directed specifically to poxvirus embodiments of Inglis' invention. As discussed above, the Petition has not accurately described the quantity of disclosure provided in Inglis' priority applications. Both the Board and the Federal Circuit were cognizant of the quantity of the disclosure contained in the Inglis applications, since both the Board and the Federal Circuit summarized the content of those applications in their respective opinions. App. 48a (Board opinion); App. 12a-14a (Federal Circuit opinion).

Both the Board and the Federal Circuit cited to the doctrine that patent disclosures are drafted to be read by a person skilled in the relevant art. The parties in this case stipulated to a very high level of ordinary skill in the art. App. 47a (Board opinion); App. 14a (Federal Circuit opinion); A 624 (stipulation). The Board found this high level of skill to be accurately reflected by the "voluminous prior art and reference material cited in the record." App. 48a.

Based on the evidence produced by the parties on the enablement issue, the Board found that: "*Falkner has not proved* that the routineer could not have practiced the subject matter of the [interference] count based on this disclosure and what was known and understood by the routineer in this art without 'undue' experimentation." App. 48a, last 5 lines (emphasis added). It can be seen that what Petitioner is asserting as legal error by the Board is, at bottom, a failure by Petitioner to prove its allegations.[5]

The Federal Circuit pointed out that enablement is a conclusion of law based on underlying findings of fact. App. 15a.[6] Upon reviewing the Board's decision finding enablement, and presented with the same set of arguments which Petitioner presents here, the Federal Circuit found that the Board had not erred. App. 15a.

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[5] Petitioner's "Question Presented" (Petition, first page) makes the unjustified and argumentative assumption that Inglis did not disclose the poxvirus embodiments of the invention or how to make and use them. The assumption built into the "Question Presented" in the Petition is itself contrary to the evidence of record.

[6] The factual inquiries which underlie a conclusion of enablement (whether or not the required amount of experimentation would be "undue" to a person of ordinary skill in the art) are set out in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), which was cited by the Board at App. 41a and applied throughout its opinion. The Federal Circuit cited these factors at App. 10a. Petitioner presents no contention that *In re Wands* is not controlling law on how enablement should be assessed.

The Federal Circuit cited and applied the familiar patent law doctrine that a patent disclosure need not teach, and preferably omits, descriptive matter which is known to those skilled in the art, citing *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.3d 1524 (Fed. Cir. 1987). App. 15a. Petitioner does not openly challenge the validity of that doctrine, which traces back to at least as early as this Court's decision in *Webster Loom Co. v. Higgins*, 105 U.S. (15 Otto.) 580 (1881)(explaining that a patent disclosure is written for a skilled artisan, and subject matter which is common and well-known need not be included). A fundamental issue which Petitioner has overlooked throughout this case is that a patent disclosure is read, not in a vacuum, but in light of what the skilled reader already knows. As pointed out by the Board, Petitioner's motions in this case erroneously focused upon what the Inglis priority applications *do not* disclose, instead of explaining how what *is* disclosed would have been understood by a skilled artisan. App. 47a. Petitioner's motions were also deficient for failing to separately address the existing state of the art as of the filing date of each of the Inglis priority applications, which were filed over a period of five years App. 31a-32a.[7]

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[7] Petitioner argues at pp. 25-27 that permitting reliance on what is already known in the art allows for *nunc pro tunc* inventions. Following Petitioner's argument to its logical conclusion, a patent drafter could never rely on what is already known in the literature, but instead would need to draft every patent specification with the detail of a production blueprint. Petitioner's argument is contrary to long-standing patent law doctrine as expressed in *Spectra-Physics*, *Webster Loom* and *In re Wands* that patent disclosures are directed towards a reader skilled in the art.

Both the Board and the Federal Circuit found, based on the evidence of record, that the experimental details asserted by Petitioner to be missing from Inglis' disclosure (such as identifying poxvirus "essential" genes from existing maps of the poxvirus genome) were readily known from the literature. A worker skilled in this art – what the Board referred to as a "routineer" - is presumptively familiar with the published literature.[8] The Board also made a factual finding that complex laboratory techniques are ordinary in the field of vaccine preparation. App. 49a.

One of Petitioner's primary arguments to the Board and to the Federal Circuit – and again in the Petition (pages 26-27) - is that the herpesvirus exemplification provided in the working examples of the Inglis priority applications would not have enabled one skilled in the art to make a poxvirus embodiment, since herpesviruses and poxviruses are very different viruses. It was also argued that Inglis had admitted, in another context during *ex parte* prosecution of its patent application, that herpesviruses and poxviruses are different (Petition, pages 7 and 13). Respondent countered these arguments before the Board with testimony and supporting evidence that a person skilled in the art, as of the relevant dates, was familiar with the differences between herpesviruses and poxviruses, and that the herpesvirus working examples provided

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[8] The presumption of familiarity with published art on the part of the hypothetical person of "ordinary skill in the art" applies normally, and was made express in this case by the parties' stipulation as to the applicable level of ordinary skill in the art A 624-625.

by Inglis could be adapted by the skilled worker to make a poxvirus embodiment. This was a contested factual issue which was the subject of conflicting expert testimony and other evidence before the Board.[9] The Board found, and the Federal Circuit specifically upheld the finding, that the differences between herpesviruses and poxviruses were well-known to the skilled worker as of the relevant dates. App. 50a; App. 14a. The Federal Circuit cited to this evidence and agreed with the Board's finding that the differences would have "*aided*" the person of skill in the art to make a poxvirus embodiment. App. 14a. Petitioner's argument disregards the fact-finding made below, and is asking this Court to reach the exact opposite conclusion on this contested factual issue.

As to Inglis' alleged "admission" about the differences between poxviruses and herpesviruses, Inglis explained to the Federal Circuit that: i) the statements being cited as "admissions" were not relevant to the issues presented in the motions before the Board; and ii) the argument was belatedly raised before the Board. The Federal Circuit declined to address this allegation, suggesting that Petitioner's argument lacked merit.

For these reasons, the Petition has made no showing that the Board or the Federal Circuit committed any reversible error of law or fact when

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[9] Respondent's expert testimony was from Dr. Michael Boursnell. A 783-815. Petitioner presented the expert testimony of Dr. Miles Carroll. A 163-244. The Board discounted the testimony of Dr. Carroll as being conclusory on the enablement issue. App. 50a-51a.

finding Inglis' priority applications to be enabling for the subject matter of the interference count. The Petition offers no compelling reason to grant a writ of certiorari as it relates to the enablement requirement of 35 U.S.C. § 112. There was no misapplication of the law of enablement.

4. The Decision Finding Written Description Support in the Inglis Priority Applications and Involved Application was Based on Correct Application of the Law of Written Description and was Amply Supported by the Evidence of Record

The findings below about which Petitioner complains are attributable to the inadequacy of Petitioner's evidence and presentation before the Board, not to legal error.

As explained by the Board, Petitioner's expert witness, Dr. Carroll, applied a legally incorrect standard of "actual possession" in the testimony he offered to the Board on the issue of written description. Dr. Carroll also incorrectly focused on how to "make and use" the invention (which concerns enablement) in his testimony alleging lack of written description. For these reasons, the Board was correct to discount the probative value of Dr.

Carroll's testimony on the issue of written description. App. 37a; App. 39a–40a.[10]

Petitioner had the burden of proof by a preponderance of evidence to prove the alleged lack of written description support for the interference count in Inglis' priority applications.[11] While Petitioner's motions alleging lack of written description were *prima facie* deficient to meet its burden due to the defectiveness of the supporting evidence and the improper legal analysis, both the Board and the Federal Circuit went on to carefully review the entire record and to consider and address the various arguments challenging Inglis' written description support for the subject matter of the interference count and for its claims in the interference.

Sufficiency of written description is a question of fact. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991), cited at App. 10a. The

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[10] As explained by the Board, Petitioner's motions attacking Inglis' priority applications also misconstrued and misapplied the law as it relates to obtaining benefit of an earlier application for purposes of priority, which is different from obtaining benefit of an earlier application for purposes of 35 U.S.C. § 119 or 35 U.S.C. § 120. App. 28a-29a.

[11] On appeal to the Federal Circuit, Petitioner alleged various grounds of procedural error on the part of the Patent and Trademark Office in its designation of Inglis as the "senior" party. This designation placed the burden of proof (by a preponderance of evidence) upon Petitioner to contest Inglis' right to rely on the filing dates of its priority applications. The Federal Circuit responded to Petitionser's assertions of procedural error by stating simply: "These arguments lack merit, and we shall not further discuss them." App. 10a.

Federal Circuit cited to declaration testimony from Inglis' expert witness, Dr. Boursnell, as support for the Board's factual findings on written description. App. 16a. The Federal Circuit also cited to decisional law that the content of a disclosure, not its length, is what is relevant to the adequacy of a written description. App. 16a.

The Petition argues that *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974) is controlling precedent overlooked by the Federal Circuit. The *Kewanee Oil* decision concerned the relationship between federal patent law and state trade secret law, and cites to the then-existing statutory language concerning the disclosure needed to support a patent. 416 U.S. 480-481. The Petition fails to explain how the subsequent Federal Circuit decisions relied upon by the Board and by the Federal Circuit in this case are inconsistent with the currently-existing statutory language of 35 U.S.C. § 112.

While the language of 35 U.S.C. § 112 requires the terms of a disclosure to be "full" and "clear" and "concise" and "exact," a body of decisional law has evolved which sets out the factual considerations for determining whether those statutory requirements are met *in a particular case*. Bypassing any discussion of the decisional law cited by the Federal Circuit, the Petition at page 25 makes a conclusory and unwarranted assertion that the Federal Circuit ignored the applicable constitutional and statutory requirements.

More specifically as to written description, the Petition fails to allege legal error in the Federal Circuit's specific holdings that neither "examples" nor "an actual reduction to practice" nor "recitation of known structure" (viral gene sequences already known in the literature) were required to satisfy the written description requirement of 35 U.S.C. § 112 on the facts of this case. App. 16a, last paragraph. In fact, the Federal Circuit was on solid ground as to each of these points.

The Federal Circuit first explained that the absence of examples does not itself render written description of an invention inadequate. App. 17a. The Petition cites no contrary decisional law for the proposition that written description support under 35 U.S.C. § 112 *does* require examples.

The Federal Circuit next explained that an "actual reduction to practice is not required" for written description support, citing *University of Rochester, supra* and *Pfaff v. Wells Elecs.*, 525 U.S. 55, 66, 119 S. Ct. 304, 142 L. Ed. 2d 261 (1998). App. 17a-19a. Petitioner concedes that "current patent law" recognizes that a reduction to practice may be either actual or constructive (Petition, page 15, footnote 16), and the Petition cites no contrary decisional law for the proposition that written description support under 35 U.S.C. § 112

necessarily requires an actual reduction to practice.[12] The Petition makes no effort to distinguish this Court's statement in *Pfaff*, cited by the Federal Circuit, that an invention can be "complete" in the absence of an actual reduction to practice. App. 19a.[13]

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[12] Petitioner criticizes Inglis' disclosure as not being "real research" (Petition, page 25). While Inglis's disclosure does not evidence an actual reduction to practice of a poxvirus embodiment, the disclosure provides "working" examples ("real research") illustrating the herpesvirus embodiment, which the Board found to provide guidance to the skilled artisan to make and use the invention including poxvirus embodiments. In addition, Respondent notes that Petitioner's patent in the interference contains Examples 1-4 (written in the present tense) and Example 5 (written in the past tense, reporting work actually done). A 116-119. Examples 1-4 are prophetic examples, and not "real research." Petitioner's priority application filed April 29, 1994 (mentioned at page 9 of the Petition) contained Examples 1-4 but not Example 5. Nonetheless, Petitioner consistently maintained its right to rely upon the filing date of the April 29, 1994 application as a date of invention in the interference. Thus, Petitioner was, like Inglis, relying upon a "constructive" reduction to practice of poxvirus embodiments in its earliest-filed patent application as the basis for priority support for the interference count. Indeed, the Petition states on page 10 that Petitioner's April 29, 1994 application "disclosed the modified poxvirus vaccine invention." On this record, Petitioner is not in a favorable position to insist that only "real research" – an actual reduction to practice - can suffice to provide an adequate written description of an invention.

[13] Petitioner continues even now to incorrectly urge an "actual" reduction to practice standard for written description, by arguing that the Inglis applications contain "no evidence that they [Inglis et al.] ever figured out how to ***actually make*** a modified poxvirus vaccine." Petition, page 23 (emphasis added). As explained by the Board, by the Federal Circuit, and by this Court in *Pfaff*, that is not the correct standard.

Lastly, the Federal Circuit explained that description of poxvirus gene sequences already known in the scientific literature was not required to support Inglis' written description. As noted above, the parties stipulated in this case that the person of ordinary skill in the vaccine art would have been familiar with the relevant poxvirus literature. The Federal Circuit pointed to Dr. Bournell's testimony and associated evidence and stated: " 'the skilled person would have been readily able to choose an essential vaccinia [poxvirus] gene' based on references that have been publicly available since 1990. The testimony of Falkner's expert, Dr. Carroll, did not refute this claim." App. 16a. In view of Dr. Boursnell's testimony, and the absence of contrary testimony, it cannot be reasonably argued that this finding lacks substantial evidence support. In connection with written description, the Federal Circuit explained that requiring disclosure of known genetic sequences would add to the bulk, but not to the quality, of patent specifications. App. 20a-21a. The Petition cites no authority that requires the recitation of known genetic sequences to satisfy the written description requirement, nor provides any policy reasons for why such a requirement should be imposed.

On pages 6, 11-13 and 22, the Petition asserts that an inconsistency exists in the Board's findings that the Inglis PCT application supports the count, but at the same time, does not anticipate claim 1 of Petitioner's patent. In response, there is no inconsistency. The interference count was defined in

the alternative as Falkner claim 1 or Inglis claim 29. See A70. Inglis claim 1 defines a vaccine comprising a poxvirus having a mutated (inactivated) essential gene. Falkner claim 29 differs from Inglis claim 1 by further reciting that the mutant poxvirus comprises a gene encoding an antigen under control of a promoter. This distinction was fully appreciated by the Board. See A77 (p. 20, ll. 16-21). The Board's opinion denying Inglis' motion asserting anticipation of Falkner claim 1 clearly indicates that the Board premised its denial on a finding that the evidence cited by Inglis had not been shown to describe a heterogene encoding an antigen "under the transcriptional control of a promoter," as recited in Falkner's claim 1. App. 62a-63a. While the Board found that Inglis had not explained how this element of Falkner's claims was present in the proffered prior art reference so as to find "anticipation" of Falkner's claims (App. 63a), that same element is not recited in the portion of the count defined by Inglis claim 29. Accordingly, Inglis was able to show support for the interference count in the earlier Inglis disclosure, while being found not to have met its burden to prove that the same disclosure contained all elements of Falkner's claim 1. Page 7 of the Petition mischaracterizes the Board's holding by stating that the Inglis' application did not disclose "modified poxvirus vaccine." What the Board found was that

Inglis had not met its burden to prove anticipation of Falkner's claims. App. 63a.[14]

The absence of inconsistency between these holdings was explained to the Federal Circuit in response to this same argument (both on original briefing and on Petitioner's request for *en banc* review) and the Federal Circuit deemed this argument to be unworthy of discussion. It is a meritless argument.

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

Petitioner's arguments are contrary to the factual findings made in the proceedings below, which are fully supported by the evidence presented to the Board. Petitioner has identified no misapplication of law to those facts by the Board or by the Federal Circuit. Accordingly, Petitioner has raised no compelling reason for grant of a writ of certiorari, and it is requested that the Petition be denied, allowing the interference judgment in favor of Respondent to stand.

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[14] The Board's wording makes clear that, in the Board's view, Inglis had not carried its burden on the motion alleging anticipation of Falkner claim 1. That is different from holding that the prior art was, in fact, non-anticipatory. Inglis did not cross-appeal that decision for the reason that Inglis prevailed on priority of invention, thereby invalidating all of Falkner's patent claims on the basis of priority of invention. Whether Falkner's claims were invalid for other reasons (such as anticipation by published prior art) had become a moot issue.

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No. 06-693

IN THE

Supreme Court of the United States

FALKO-GUNTER FALKNER, GEORG HOLZER, and FRIEDRICH DORNER,

Petitioners,

v.

STEPHEN C. INGLIS, MICHAEL E.G. BOURSNELL, and ANTHONY C. MINSON,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF

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STATEMENT PURSUANT TO RULE 29.6

Petitioners' corporate disclosure statement was set forth at page *ii* of the Petition for a Writ of Certiorari, and there are no amendments to that statement.

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INTRODUCTION

The *Falkner v. Inglis* decision should not stand because the Federal Circuit has not heeded the established jurisprudence of this Court regarding the disclosure requirements that are incumbent on all patent applicants. Should this decision stand, patent applicants will be permitted to obtain patents that do not promote the progress of science, that claim subject matter outside of their discovery, and that are not supported by a description of the invention and of how to make and use it in the requisite full, clear, concise and exact terms. Absent review and a reversal, this decision will permit the issuance of patents that are not in compliance with the U.S. Constitution and the patent laws. This decision is a direct result of the continuing conflict at the Federal Circuit on the scope and nature of the disclosure requirements for patent applicants.

Writing as if the dispute among the Federal Circuit judges on the issue of written description did not exist, Respondents in opposition refer to an "alleged 'conflict.'"[1] As pointed out in the Petition, however, no fewer than five Federal Circuit judges have strongly voiced their dispute, and their conflict has drawn the attention of scores of academics and practitioners who have written about the conflict. For example:

> As to this requirement, a debate has been brewing in the U.S. Court of Appeals for the Federal Circuit – the appellate court responsible for appeals in all cases – over whether the patent statute contains a separate "written description"

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1. See footnote 2 at page 3 of Respondent's Brief in Opposition to Petition for Writ of Certiorari ("Opposition Brief"). See also Opposition Brief at page 1: "Petitioner suggests an intra-Federal Circuit controversy concerning whether the 'written description' requirement of 35 U.S.C. § 112 is separate from the 'enablement' requirement of 35 U.S.C. § 112."

> requirement, or whether the description requirement is simply part and parcel of the requirement that the patent enable those in the art how to make and use the invention. The debate has been particularly fierce in the area of patents directed to pharmaceutical and biotechnology inventions. Recently, over vigorous dissenting opinions, the court has declined to address this issue as en banc court, leaving open the question of whether the Supreme Court will weigh in.

Petition at page 20, *quoting* Vernon M. Winters & Elizabeth S. Weiswasser, *The Written Description Requirement: Ripe Enough? Or Is More Percolation Required?* 51 Fed. Law. 20 (2004).

Respondents next allege that the Petition "does not clearly articulate the alleged 'conflict'" nor spell out the connection between this case and the "alleged conflict." Opposition Brief at page 3, footnote 2. Again, they are incorrect. The foregoing passage, the cited dissents, and numerous other parts of the Petition all make clear how the conflict over whether there is a separate written description requirement or whether it is merely part of the enablement applies to this case.

In Petitioner's view, there can be no dispute as to what the panel did. By conflating the written description and enablement requirements of 35 U.S.C. § 112, the panel effectively eliminated the requirement of this Court, the statute, and other panels of the Federal Circuit that an application as filed must contain a written description of the invention and how to make and use an invention in full, clear, concise and exact terms. Rather, the panel subscribed to the competing view that there is only an "enablement requirement" that permits virtually every detail of a claimed invention to be filled in by hindsight citation to "accessible

literature sources[2]" that provide published compositions[3] that are not identified nor suggested in the application. The panel's pronouncement of a new 'written description requirement' for biotechnology inventions radically alters the Constitutionally-mandated bargain between patentees and the public from one that will "promote the Progress of Science" to one that will not. The specific points raised by Respondents are addressed below.

NEW POINTS RAISED BY RESPONDENT

The ongoing, tumultuous dispute at the Federal Circuit

At pages 3-5 of their Opposition Brief, Respondents contend that the conflict at the Federal Circuit on written description has no bearing on this case. Respondents support their position by citing to a lack of dissent in the Federal Circuit decision and the denial of the petition for rehearing and rehearing *en banc* issued in the late summer of this year. Respondents, however, did not address the adverse impact the Federal Circuit's conflicting written description jurisprudence has on the patent system.

In response, Petitioners first reiterate that the Federal Circuit panel stated that the Board of Patent Appeals and Interferences ("the Board") had not properly articulated the written description standard in rendering its decision. App. 15a. While the panel dismissed this error as being harmless, a legal inquiry that starts from a wrong premise is exceedingly unlikely to be proper.

Second, as noted by Respondents at page 4, the *Falkner v. Inglis* decision was authored by Circuit Judge Gajarsa, who

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2. App. 21a.

3. Here, the compositions would be poxvirus essential genes as they exist in nature. Importantly, not even the literature sources disclose which essential regions to use to make the contested poxvirus vaccine invention nor the complementing cells needed to grow the poxviruses. See Petition at page 24, fn.19.

has joined in dissents arguing that a separate written description requirement creates confusion and is an ill-defined doctrine. *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1326 (Fed. Cir. 2004), *cert. denied*, 543 U.S. 1015 (2004); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 982 (Fed Cir. 2002). The *Falkner v. Inglis* decision is nothing less than a direct repudiation of the competing ideology[4] at the Federal Circuit. Hence, litigants are now confronted with directly competing ideologies embodied in diametrically contrary decisions. Federal Circuit panels of either or mixed ideologies are now fully armed with competing precedential decisions upon which to support their particular views.

In this case, the panel's decision did not explain whether Inglis provided a full, clear, concise and exact description of a poxvirus vaccine invention, and of how to make and use it. Rather, the decision focused on general types of description that are not needed in patent applications.[5] When every type of description discussed by the panel is missing in the Inglis priority applications, and there is no alternative disclosure of any detail concerning poxvirus vaccines to make up for their absence, it can be fairly said that the panel did not believe that Respondents needed to provide in their applications a written description of the poxvirus vaccine

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4. The competing ideology at the Federal Circuit requires a detailed written description of the invention in addition to an enabling disclosure, whereas the ideology prevailing here requires only enablement, and not a full, clear, concise and exact written description of the invention. Enablement, however, can be supplemented by alleged outside knowledge in the field. By its very nature, this latter ideology is quite susceptible to hindsight 'reinvention' of patent applications.

5. The Federal Circuit panel opined that (1) examples are not required, (2) there need not be an actual reduction to practice, which refers to invention actually made and shown to work, and (3) recitation of known structure is not required. App. 17a-21a.

invention and of how to make and use it in "full, clear, concise, and exact terms." In other words, this section of the patent laws has been effectively removed as a requirement for patent applicants.

Finally, Respondents on pages 3-4 argue that the Federal Circuit summarily dismissed the petition for rehearing and rehearing *en banc* and saw no urgency in that petition. Such an argument is speculative, and does not tell the whole story. It is beyond dispute that the Federal Circuit has not clarified its law on written description in an *en banc* manner in any case, and will not provide Petitioner with the relief sought here to correct the errors made by the panel. Indeed, one Federal Circuit Judge has stated, "I do not believe that every error by a panel is enbancable. A panel is entitled to err without the full court descending upon it." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 469 F.3d 1039, 1043 (Fed. Cir. 2006) (Lourie, J., concurring) (discussing the denial of a petition for rehearing *en banc* on a claim construction issue). What is a patent holder to do in such situations?

Petitioners' characterization of the Inglis applications was accurate

At pages 5-6, Respondents argue that Petitioners have mischaracterized the Inglis priority applications. Respondents cite to their alleged generic disclosure to all viruses, their herpesvirus disclosure and examples, their three passages mentioning poxviruses, and purported findings by the Board. Petitioners believe these issues were identified and accurately discussed on pages 8, fn 7; 11-13 and 23-25 of the Petition to this Court. In opposition, Respondents cite to no disclosure beyond the two sentences quoted in the Petition. As stated before, the first sentence referenced a type of poxvirus (*i.e.*, vaccinia) as a possible starting material for deriving a vaccine in the future, and the second sentence expressly acknowledged that a poxvirus vaccine had not been made:

> As another example the virus may be derived from an orthopox virus [types of poxviruses], for example, vaccinia virus, which again may comprise a heterologous sequence encoding an immunogen derived from a pathogen.

Inglis PCT application at page 6, line 26 to page 7, line 4. A420-21.

> No vaccinia virus [a type of poxvirus] with a deletion in an essential gene has yet been produced, but such a virus, deleted in an essential gene as described above, with its complementing cell for growth, would provide a safer version of this vaccine vector.

Inglis PCT application at page 15, lines 1-5. A429.

Respondents provided nothing more than this.

The decision on enablement

Respondents' argument is set forth at pages 6-11 of their Brief. Respondents argue that enablement was satisfied by the stipulated high level of skill in the poxvirus art, the contents of the prior art that need not be disclosed in a patent application, and a detailed disclosure of herpesvirus vaccines. Respondents allege that their prosecution statement[6] concerning the differences between herpesviruses and poxviruses was not relevant and was belatedly presented. Respondents' rebuttal argument fails, however, because neither the Board nor the Federal Circuit panel addressed this prosecution statement.

The important point here is that Respondents seek to rely upon "accessible literature sources" outside of their application to extrapolate herpesvirus teachings into poxvirus teachings, and thereby provide descriptive support for a patent grant to the contested poxvirus vaccine invention.

6. See Petition at pages 26-27.

Respondents' entire case thus is based upon an allegation of what the skilled person would have been able to,[7] rather than upon what Respondents actually did and did not disclose. To summarize, the prior art and the skill in the art are not part of the patent specification. Herpesvirus vaccines are not the invention in interference, and herpesviruses were represented by Respondents to be significantly different from poxviruses. What the patent statute calls for here is disclosure in the specification of the poxvirus vaccine invention and how to make and use it in full, clear, concise and exact terms. The Constitution calls for patent applicants to be awarded only with patents to their discovery, not the discoveries of others, in order to promote the progress of science. The award to Respondents here is based on a wholesale reliance on information in the prior art combined with disclosure of a different invention, which satisfies neither the Constitution nor 35 U.S.C. § 112.

The decision on written description

Respondents discuss written description on pages 11-18 of their Brief. At page 12, Respondents urge that the Board and the Federal Circuit panel carefully reviewed the entire record, which is open only to speculation by the parties. What is clear, however, is that (1) the Board issued a non-anticipation holding, unappealed by Respondents, that is diametrically opposed to the judgment affirmed by the Federal Circuit, and (2) the Federal Circuit panel did not discuss the impact of this Board holding in its decision.[8]

7. *See U.S. Industrial Chemicals v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668, 677-78 (1942) (noting that if an invention was as broad as professed in litigation, "[t]he inquiry at once arises, if this were so, why he did not say so" in the patent application.). Neither the Federal Circuit nor the Board undertook such an inquiry.

8. The parties agree that the Federal Circuit did not address this holding, but differ on the reason why. See Petition at pages 11, 12 and 22; Opposition Brief at pages 17-18.

Respondents try to explain away the Board's non-anticipation holding as being premised on the Board not finding that the Inglis PCT application described a "heterogene" encoding an antigen. See Respondents' Opposition Brief at 17. Although Respondents do not explain what a heterogene is, Petitioners presume Respondents are referring to a gene from a foreign source, such a bacterial gene or another type of virus.[9]

More importantly, however, Respondents' story cannot be squared with the Board's decision. In rendering its non-anticipation decision, the Board focused on the citations provided by Respondents. The Board found that the citations provided by Respondents were directed to the poxvirus prior art, not the poxvirus vaccine invention of the interference. Indeed, the Board stated:

> Nevertheless, the disclosure at page 14 is directed to the ability of vaccinia virus, a particular, well-known poxvirus, to carry and express genes from various pathogens" and the use of a vaccinia virus modified to carry and express genes from various pathogens as an effective vaccine in animals. Inglis has failed to explain why we should construe the referenced disclosure as being directed to a defective poxvirus lacking a function imparted by an essential region of the parental poxvirus. Moreover, the remainder of the context of the cited portion of the reference discusses "the reluctance to use an unmodified vaccinia virus on large scale in humans." We do not understand that

9. There is no requirement for a "heterogene" in the poxvirus vaccine invention of the interference, rather its presence is purely optional. See Petition at page 8, fn.8. The count, which defines the contested invention, does not expressly or implicitly require a "heterogene." Moreover, Petitioners' claim 1 (which is part of the count) and the Board decision does not expressly or implicitly require or discuss a "heterogene."

> an "unmodified vaccinia virus" would be understood to mean a "defective poxvirus that lacks a function imparted by an essential region of its parental poxvirus." App. 63a.

This discussion is entirely consistent with Petitioners' position, namely that the Inglis priority applications discuss poxvirus prior art, but do not disclose the poxvirus vaccine invention in full, clear, concise and exact terms. Rather, the Inglis priority applications only contain the two sentences discussed above.

The Federal Circuit did not address this Board holding even though it was brought to their attention. Rather, the Federal Circuit panel quoted the language (see, e.g., page 14 of the Inglis PCT application, A428-29) discussed by the Board above. However, the panel quoted from application page 14 in order to support affirmance. App. 13a. Thus, text that the Board determined only concerned the poxvirus prior art and not the contested poxvirus vaccine invention was used by the Federal Circuit as text that disclosed the contested poxvirus vaccine invention. Logically, this situation cannot hold.

Again, absent action by this Court, Respondents' patent applications will continue to be held to both describe and not describe the poxvirus vaccine invention of the interference. Such as status should not be permitted to continue.

CONCLUSION

In sum, the Federal Circuit panel would award a patent to applicants who provide nothing more than a two sentence wish for others to conceptualize, design and make the contested poxvirus vaccine invention. The Federal Circuit panel bases this award on patent applications that the Board expressly found did not describe poxvirus vaccines, a determination which Respondents have not appealed. Rather, Respondents' patent applications concern herpesvirus, a technology which Respondents represented to the Patent Office does not pertain to poxvirus. The decision of the Federal Circuit panel would not award Respondents with a patent to their discovery, but would rather award Respondents with a patent to the discovery of others, namely Petitioners.

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